Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM, PRODUCTS LIABILITY LITIGATION : MDL NO. 2327

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AND VARIOUS OTHER CROSS-NOTICED ACTIONS

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May 22, 2013

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Videotaped 30(b)(6) deposition of DANIEL F. BURKLEY, MS taken pursuant to notice, was held at the law offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:23 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public for the State of New Jersey.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.951.5672 fax
deps@golkow.com

APPEARANCES:

ANDERSON LAW OFFICES, LLC
BY: BENJAMIN HOUSTON ANDERSON, ESQUIRE
1360 West 9th Street
Suite 215
Cleveland, Ohio 44113
(216) 592-8384
ben@andersonlawoffices.net
Representing the Plaintiffs

KLINE & SPECTER, P.C.
BY: ROGER CAMERON, ESQUIRE
The Nineteenth Floor
1525 Locust Street
Philadelphia, Pennsylvania 19102
(215) 772-1000
roger.cameron@klinespecter.com
Representing the Plaintiffs

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC
BY: PAUL N. DAVIS, ESQUIRE
1020 Highland Colony Parkway
Suite 1400
Ridgeland, Mississippi 39157
(601) 948-5711
paul.davis@butlersnow.com
Representing Johnson & Johnson and Ethicon and the Witness

APPEARANCES VIA TELEPHONE:

PAM MAY LAW FIRM, P.S.C.
BY: MATTHEW HALL, ESQUIRE
P.O. Box 1439
Pikeville, Kentucky 41502
(606) 432-0400
mhall@pammaylaw.com
Representing Altman, McGuire, McClellan & Crum, P.S.C. and Rick A. McClellan

VIDEOTAPE TECHNICIAN:
DAVID LANE

ALSO PRESENT:
JULIE FILARSKI, Anderson Law Offices, LLC
MICHAEL KAUFFMANN, Precision Trial Solutions

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I N D E X

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E X H I B I T S

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NO.	DESCRIPTION	PAGE
T-268	Curriculum Vitae, 3 pages	11
T-269	E-mail chain, top one dated 03 Apr 2009, Bates stamped ETH.MESH.02184435 and ETH.MESH.02184436	24
T-270	Johnson & Johnson Credo, 1 page	34
T-271	"Our Ethical Code for the Conduct of Research and Development," 1 page	69
T-272	E-mail chain, top one dated 01 Mar 2012, Bates stamped ETH.MESH.07226377 through ETH.MESH.07226379	95
T-273	E-mail chain, top one dated 29 Feb 2012, Bates stamped ETH.MESH.04038180 and ETH.MESH.04038181	132
T-274	E-mail chain, top one dated 05 Mar 2012, Bates stamped ETH.MESH.04937874 through ETH.MESH.04937876	165

T-275	Response to e-mail from C. Huntington, March 6, 2012, Bates stamped ETH.MESH.07212397 and ETH.MESH.07212398	169
T-276	Memo dated March 12, 2012, Bates stamped ETH.MESH.07205369 and ETH.MESH.07205370	187
T-277	Article entitled "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants," Arnaud Clave, et al., 10 pages	198
T-278	E-mail chain, top one dated 07 Mar 2012, Bates stamped ETH.MESH.07226404 and ETH.MESH.07226405	198
T-279	Interim report mesh explants pelvic floor repair, April 2008, Bates stamped ETH.MESH.00006636	267
T-280	Intermediate Report -- Prolapse Mesh Explants 6/2009, Bates stamped ETH.MESH.02157879 and ETH.MESH.02157880	275

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer

Request for Production of Documents

Stipulations

Question Marked

THE VIDEOGRAPHER: We're now on the record. My name is David Lane. I'm a videographer for Golkow Technologies. Today's date is May 22, 2013, and the time is 9:23 a.m. This video deposition is being held in Morristown, New Jersey In Re: Ethicon, Inc. Pelvic Repair Systems. Our deponent today is Daniel Burkley.

Counsel will be noted on the stenographic record.

The court reporter today is Ann Marie Mitchell, and will now swear in the witness.

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DANIEL F. BURKLEY, MS, after having been duly sworn, was examined and testified as follows:

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THE VIDEOGRAPHER: Please begin.

MR. HALL: I would like to note before we begin that Altman, McGuire, McClellan and Crum, P.S.C., as well as Dr. Rick McClellan individually, have objected to the cross-notice of these video depositions but that that objection hasn't yet been heard by the Court.

MR. ANDERSON: So noted.

MR. HALL: Thank you.

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EXAMINATION

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BY MR. ANDERSON:

Q. Good morning, Mr. Burkley.

A. Good morning.

Q. Good to see you again. I took your deposition back in October of 2012, probably right here in this same office.

Do you recall that?

A. Yes, I do.

Q. And at the beginning you may recall that I gave a few ground rules. And since I know now that you've been through the deposition process, the only one that I would reiterate is that if you answer one of my questions, we're going to assume that you understood it unless you tell me I need to clarify it or otherwise restate it; is that fair?

A. Yes.

Q. You have been an employee at Ethicon since 1979. Correct?

A. That is correct.

Q. So you're in your 34th year?

A. Yes.

Q. And you were a senior scientist in

corporate product characterization for many years, and then at some point in time, corporate product characterization was reorganized within R&D. Correct?

A. That's correct.

Q. And that department is now called analytical characterization; is that correct?

A. That's one of the departments that spun off from corporate product characterization.

Q. And are you currently a senior scientist in the analytical characterization department?

A. My current title is principal scientist.

Q. And you operate the infrared optical microscopy lab, and you characterize polymers, materials, competitor products, as well as characterizing the causes of failure on return product complaints for quality improvement; is that correct?

A. That is correct.

Q. And you are the person at Ethicon/Johnson & Johnson with primary responsibility for performing optical microscopy analysis of surgical meshes in terms of the

analytical characterization group; is that correct?

MR. DAVIS: Object to the form.

THE WITNESS: I am one such resource. I'm not the only resource.

BY MR. ANDERSON:

Q. At the Ethicon Somerville location, who other than yourself currently performs optical microscopy or infrared analysis of surgical meshes?

A. I would be one such individual that performs infrared analysis from a research point of view. As far as optical microscopy, there are other departments that do have optical microscopes, so it's conceivable that they could do optical measurements on meshes or other devices besides myself.

Q. And I appreciate that it may be conceivable, but in all practical purposes, can you and I agree that you are the primary person who performs optical microscopy and IR analysis of Ethicon surgical meshes currently?

A. For analytical characterization, yes, I do.

Q. I will mark my first T exhibit as Exhibit Number 268, which was sent to us and represented as your current CV.

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(Deposition Exhibit No. T-268, Curriculum Vitae, 3 pages, was marked for identification.)

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BY MR. ANDERSON:

Q. Do you have that in front of you?

A. I do.

Q. And is that in fact a current copy of your CV or resume?

A. Yes, it is.

Q. Have there been any significant additions, changes, modifications since we last met in October of last year?

A. I believe that this is the updated version since October.

Q. Right. And I guess I didn't bring the other one to compare.

I was just wondering if anything comes to mind of significance in your CV that has changed or been added since we met in October?

A. Oh, since we met in October. Well, I've updated it, because I believe the previous one was significantly older.

Q. Yes. I remember you saying that at

the time.

A. So yeah. So I have updated it up to at least 2012.

Q. I notice under your "Publications" and ("Articles)," you have, on the second page of your CV, under the third publication listed -- actually, let's make it the fourth one, the last one.

A. Uh-huh.

Q. "In-Vitro Antimicrobial Evaluation of Coated VICRYL Plus Antibacterial Suture (Coated Polyglactin 910 with Triclosan) Using Zone of Inhibition Assays," in the publication Surgical Infections.

A. Yes.

Q. Is that a peer-reviewed publication?

A. I can't answer that question, I don't know.

Q. Do you have a copy of that in your files somewhere that you could provide to us?

A. I had a copy that I had in my office last year, but I've changed locations and I don't believe I have it anymore.

Q. Would you do me a favor and agree that after the deposition, at a reasonable point in

time, that you would go and do a thorough search to see if you can find a copy of that --

A. Sure.

Q. -- either in electronic form or hard copy and provide that to counsel?

A. Okay.

MR. ANDERSON: And, Counsel, if I could just follow-up with you after the deposition, I'll follow up with you after the deposition and I'll just send you an e-mail, if that's okay, and remind us that we're going to have a search for that. Okay?

MR. DAVIS: Sure.

MR. ANDERSON: Thank you.

BY MR. ANDERSON:

Q. And if you look at the next page, I see, one, two, three, four, five articles, and the first author is Meng Deng?

A. Yes.

Q. Who is also an Ethicon employee.

A. He is.

Q. Correct?

These publications, one is in the publication Biomaterials.

That's a peer-reviewed publication?

A. I believe so.
Q. Do you have a copy of any of these publications listed on page 3 of your CV?
A. I may have copies of the abstract but not the actual articles.
Q. Last time you and I met, we talked about the fact that Johnson & Johnson/Ethicon has a database of documents and scientific literature.
A. They do.
Q. Given that yourself and Meng Deng were authors in these publications, would you anticipate that Johnson & Johnson/Ethicon would have this contained within this scientific literature database?
A. They may. They're not Ethicon documents, per se, but it's possible that these articles would be in there.
Q. And not all articles, scientific journals, that are in Johnson & Johnson/Ethicon's database are Johnson & Johnson/Ethicon studies. Correct?
A. I don't know the answer to that question.
Q. So there's the one article at the top of page 3 of your resume published in Biomaterials.

The next one is -- well, strike that. Let me go back to that first one.

The title is "Effect of Load and Temperature on in-vitro Degradation of Poly(glycolide-co-L-lactide) Multifilament Braids."

Do you see that?

A. I do.

Q. Was that a study that was done internally at Ethicon?

A. Yes.

Q. What was the purpose of doing that study?

A. To gain a better understanding of the absorbable polymer system based on glycolide lactide under in vitro conditions.

Q. And what in vitro conditions were used?

A. I'd have to refresh my memory with the article. I didn't actually conduct the in vitro experiments.

Q. What was your role in the scientific research analysis and conclusions that may have been reached in that Biomaterials publication?

A. I provided SEM analysis of test articles after they were exposed to in vitro

conditions.

Q. What type of in vitro conditions? Are we talking humans? Are we talking animals?

A. Well, in vitro would be artificial.

Q. Oh, in vitro, I'm sorry. Yes.

So would that have been in the laboratory in mechanical conditions or in wet solutions, what?

A. They would have been in buffered solutions.

Q. Was this in relation to the Vypro mesh?

A. I don't know specifically if it was related to mesh.

Q. Is that particular chemical that's listed there, the polyglycolide-Co-L-lactide, known by other names?

A. Yes. Known as polyglactin 910.

Q. And polyglactin 910 is the absorbable component in the absorbable suture Vicryl. Correct?

A. That is correct.

Q. Which is the absorbable component, along with polypropylene, in the hernia mesh known as Vypro made by Ethicon/Johnson & Johnson. Correct?

A. That is correct, yes.

Q. Polyglactin 910 is also an additive component to TVT SECUR, a sling product for SUI made by Ethicon and Johnson & Johnson. Correct?

A. Yes, it is.

Q. That publication was in 2005, and in the next publication in 2006, also with the same authors except for Xu, X-U, it also appears to address in vitro degradation of polyglactin 910.

Am I reading that correctly?

A. Yes.

Q. This appears to be a book chapter, because it has, "chapter titled: Degradation Mechanisms."

Would that be correct?

A. I believe so, yes.

Q. And you don't know if you still have a copy of that book?

A. I never got a copy of the book.

Q. Okay.

Out of those authors, who is the most likely person -- well, let me back up a minute and strike that question.

J. Zhou, is that how you pronounce Z-H-O-U?

A. I believe it's pronounced Zhou.
Q. Zhou. Interesting.
And then there's G. Chen.
Are Zhou and Chen also Ethicon employees?
A. They are.
Q. Who of those authors is the most likely to have the book from which this chapter, Degradation Mechanisms, is born?
A. That would be the first author.
Q. So Meng Deng is the most likely person to have a copy of these five -- yes, five articles on page 3 of your resume?
A. Yes. As the principal author, I would expect him to have a copy.
Q. The next article or publication underneath that one is in Polymer Preprints.
Do you know if that's a peer-reviewed publication?
A. I believe it is.
Q. You know what I mean by peer reviewed. Correct?
A. Yes.
Q. Again addressing polyglactin 910 in vitro degradation?

A. Yes.
Q. The next article also addresses polyglactin 910 degradation that was published in Acta Biomaterialia?
A. Yes.
Q. And Acta Biomaterialia is a publication by a materials industry group or corporation. Correct?
A. I don't know that for a fact.
Q. Have you heard of the gold medal award that Acta Biomaterialia gives out each year to some person that they consider to be a leading professional in the field of biomaterial research?
A. I'm unfamiliar with that award.
Q. The next and last article is also Polymer Preprints, dealing with polyglactin 910 again. Correct?
A. Yes.
Q. In any of these -- strike that.
In all of these publications and the work that went into them, were you performing basically the same duties that you mentioned before, that you were doing SEM analysis of test articles and looking at the in vitro conditions of polyglactin 910 in buffered solutions?

A. My role would have been to do the SEM examinations of the test articles after they had been exposed to in vitro conditions.

Q. So did you do SEMs before and after?

A. In most instances, I believe I did.

Q. Was there any attempt in the research that went into these publications regarding the degradation of polyglactin 910 to look at and analyze the degradation of any other material other than polyglactin 910? For example, if this was involving the Vypro product, did you look at the degradation in vivo of both the Vicryl as well as the polypropylene?

MR. DAVIS: Object to the form.

THE WITNESS: No, I do not believe so.

BY MR. ANDERSON:

Q. In your 34 years at Ethicon, have you ever been asked to perform SEM analysis of Ethicon/Johnson & Johnson polypropylene surgical mesh?

A. Yes, I've looked at surgical mesh.

Q. And have you ever in those 34 years been asked to conduct a study to look at in vivo or in vitro degradation of polypropylene other than

your seven-year dog study?

MR. DAVIS: Object to the form.

THE WITNESS: No, I have not conducted such a study or have -- nor have I been asked to conduct such a study.

BY MR. ANDERSON:

Q. Have you ever felt the need during your 34 years at Ethicon/Johnson & Johnson to go to your superiors or your colleagues within your company and suggest that a polypropylene degradation study be performed, either in vitro, in vitro or both?

A. No, I have not taken such an initiative by myself. That would be primarily a clinical concern, and such a study would best be performed under clinical direction or preclinical direction.

Q. It may be performed under preclinical direction, but as we've seen with these studies and other things that are done within your company in terms of analytical characterization, you would be the one -- or strike that.

Even though it may be of clinical concern, you are often asked to perform SEM or IR analysis on products within the company, even if

it's pertaining to a clinical matter. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: There have been instances when I've been asked to perform that as a resource, yes.

BY MR. ANDERSON:

Q. So just because it may be direct -- strike that.

Just because a particular study might be directed by clinical, that doesn't mean you wouldn't be involved. Correct?

A. I'm sorry, could you rephrase that again?

Q. Sure.

We're talking now about whether or not you were ever asked to perform any sort of analysis during your 34 years at Ethicon of polypropylene mesh or sutures manufactured by J&J and Ethicon or its competitors --

A. Yes.

Q. -- to look at either in vitro or in vivo degradation, and you said you'd never been asked to do that.

My follow-up question was, just to put us back into our frame of reference --

A. Right.
Q. -- have you ever asked or addressed the issue with your colleagues or your superiors within Ethicon as to whether or not a degradation study should be performed on polypropylene?
A. No, I've not taken such an initiative.
Q. In your 34 years at Ethicon, are you aware of anyone within Johnson & Johnson and Ethicon who took the initiative to do a degradation study in vitro or in vivo of Ethicon/Johnson & Johnson's polypropylene mesh or sutures?
MR. DAVIS: Object to the form.
THE WITNESS: I'm only familiar with the dog study that involved Prolene suture and at least two other competitors and perhaps another suture.
BY MR. ANDERSON:
Q. And that was 25 years ago?
A. I believe that was started around 1985, yeah.
Q. So it was almost 30 years ago. Okay.
Other than that one suture study in a dog -- and what part of the dog was that in?
A. I don't know specifically.

Q. It was cardiac, wasn't it? Does that refresh your memory?

A. Yeah, I believe it was a cardiac.

Q. So other than a cardiac suture in a dog heart in 1985, just to make sure we're clear for the record, you're not aware in your 34 years at Ethicon of anyone at Ethicon or Johnson & Johnson initiating a degradation study of its polypropylene sutures or meshes; is that correct?

MR. DAVIS: Object to the form.

THE WITNESS: I personally am not aware of any such studies, no.

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(Deposition Exhibit No. T-269, E-mail chain, top one dated 03 Apr 2009, Bates stamped ETH.MESH.02184435 and ETH.MESH.02184436, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. Handing you what we will mark as Plaintiff's Exhibit 269, T-269. I'm just going to reference the second page of the document. The last four of the Bates on the cover are 4435.

I'm just going to reference the last

paragraph on page 2, which ends in 4436.

By way of reference, if you turn -- and I apologize, if you'll turn back to the front page just to get us oriented, the -- about a quarter of the way down on the page, it has "FYI," and then underneath that it says, "Mark Stachowski."

Who was he? What was his title in 2009 at Ethicon?

A. He was an associate -- excuse me -- an associate director of analytical characterization.

Q. Was he a colleague, a direct report, a supervisor?

A. He was basically the department manager.

Q. So would he have been your boss, your supervisor?

A. Yes.

Q. And this e-mail was sent on April 1, 2009, correct, just to orient us?

A. That's the date of the e-mail, yes.

Q. So just want to turn to the second page, and the last paragraph.

Are you with me, where it begins, "Additionally, Daniel Burkley"?

A. Yes.
Q. "Additionally, Daniel Burkley, M.S., will report to me and lead an increased focus in Microscopy, including but not limited to SEM," and that's scanning --
A. Electronic.
Q. -- electron microscopy, "AFM."
AFM, which is --
A. Atomic force microscopy.
Q. "IR," infrared. Correct?
A. Yes.
Q. "Microscopy and correlation with," is it Raman?
A. Raman.
Q. "Raman Microscopy."
What is AFM? I guess a better way of saying it is, I'm familiar with SEM, I'm familiar with AR and I'm vaguely familiar with AFM, but I'm not with Raman at all. So I was going to have you explain what AFM is, and then we'll do Raman.
A. Oh. AFM, again, stands for atomic force microscopy. It's a surface examination technique where you use a cantilever, which is basically a very small, minute mechanical pointer with a very fine tip to basically trace the

topography. And basically the readings of that, in terms of how high or how low the needle goes, is basically converted to a surface map. And that basically is the equivalent image that you would have -- you would see to compare with either optical or SEM.

Q. So if it was a smooth, flat surface, the readout would be a smooth, flat line; whereas if it was a rough or undulating surface, then you would have a readout that would mimic the topographical nature of the device that you're --

A. Correct.

Q. Okay.

So, for instance, if it was a surgical mesh that you were performing AFM analysis on, if it was a smoother mesh, that would give you a readout with a more flat line, and if it was a mesh that was -- had a rougher topography, if you will, then it will give you a readout that would mimic that. Correct?

A. Yes.

Q. What's the purpose of performing AFM as you understand it for surgical meshes at Ethicon/Johnson & Johnson?

A. I am not --

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of any AFM studies on surgical meshes.

BY MR. ANDERSON:

Q. I guess that would have been a better question.

Do you perform AFM on surgical meshes?

A. I do not.

Q. What is Raman microscopy?

A. Raman microscopy is in many ways a counterpart to infrared microscopy, where Raman is used instead of infrared. Raman spectroscopy measures vibrations of bonds that have no dipole moment, whereas infrared measures the vibrations of bonds that do exhibit a dipole moment. So in many ways, Raman is a complimentary technique to infrared.

Q. Explain, please, what a dipole moment is?

A. In a molecular environment or in a molecular structure, you have atoms that are bonded. For most organic materials, you're talking about carbon combined with oxygen or nitrogen or hydrogen. And each of the atoms has different

electronegativity. When an atom is bonded to another atom that's of the same type, such as carbon to carbon, there is no net dipole. There is no net difference in electronegativity. When you're -- when a carbon is bonded to, say, an oxygen, oxygen hides a higher electronegativity. It would, therefore, tend to draw electrons more around the oxygen atom than for the carbon. That would then exhibit a dipole moment.

Q. Do you perform Raman microscopy on polypropylene?

A. I have not performed Raman spectroscopy or Raman microscopy.

Q. Would Raman microscopy be an analysis that would be helpful in determining whether or not the molecular bonds of polypropylene exhibit carbonyls under various conditions?

A. It could possibly be used for that. The sensitivity would be weak, but it still may pick up some.

Q. What would be the better test in order to look for carbonyls in terms of molecular analysis of polypropylene under certain conditions?

A. Infrared would be a more sensitive test as compared to Raman.

Q. And what's the difference between IR, infrared, and FTIR, Fourier?

A. The Fourier transform, which is what FT stands for, that technique was developed in the late '70s/early '80s. And it was a revolutionary technology that enhanced infrared in terms of both the speed of which it can scan and could also take advantage of that by increasing the signal to noise based on the square root of the number of scans it took. I can go into the theory if you wish.

Q. More important at this point in time is to find out whether or not you have been asked to perform FTIR analysis of any of Johnson & Johnson/Ethicon's polypropylene sutures or meshes?

A. Yes.

Q. And under what circumstances have you been asked to perform FTIR analysis of polypropylene manufactured by Ethicon and Johnson & Johnson?

A. Primarily for material identification.

Q. Meaning by that, if I'm understanding you correctly, that you've been asked at times to perform FTIR analysis of a particular polypropylene product in order to determine if it is what it's supposed to be. Correct?

A. Yep. That's one example, yes.
Q. Is this our Prolene suture or is this some other manufacturer's polypropylene suture. Correct?
A. Yep, that's another example.
Q. Is it correct that you have never been asked nor have you taken upon yourself to perform FTIR analysis of polypropylene meshes or polypropylene sutures either manufactured by J&J/Ethicon or a competitor for looking at degradation of the polypropylene?
A. I have been asked to look at explanted material.
Q. On how many occasions?
A. Well, the one that I remember most clearly would have been the dog study.
Q. Since the dog -- strike that.
Since the time of the completion of the dog study in 1985, have you been asked by anyone at Ethicon and Johnson & Johnson or taken it upon yourself to perform FTIR analysis of polypropylene fibers, either manufactured by Johnson & Johnson/Ethicon and/or a competitor, for purposes of looking at surface degradation?
MR. DAVIS: Object to form.

THE WITNESS: I don't recall. If I have, it would have been in that same time frame as the dog study. So certainly not -- nothing in any recent history, like within the last 15 or so years. But it's possible I may have looked at some material in the '80s.

BY MR. ANDERSON:

Q. Now, you have done FTIR analysis for specification verification on certain mesh products manufactured by Johnson & Johnson and Ethicon. Correct?

A. Well, material identification tests, it's possible a protocol may have required an identity as a specification. And I've certainly looked at raw materials.

Q. What was the purpose of looking at the raw materials under FTIR analysis?

A. Primarily part of research, whether they were compounding new materials or making blends or making devices and wanted to look for evidence of, you know, material identification and/or to look to see if there were additives present or residual lubricants.

Q. In other words, if I'm hearing you correctly, there have been times that you've been

asked to perform FTIR analysis on certain polypropylene mesh or mesh fibers manufactured by Johnson & Johnson and Ethicon in which you would look to see whether or not certain manufacturing additives were there and in what amount. Yes?

A. Well, not from a manufacturing environment. From a research environment, a development environment.

Q. And when you've been asked to use FTIR on residuals, by residuals do you mean surfactants and other things that may have been added to the manufacturing process to see if they are there or if they are there, in what amount?

MR. DAVIS: Object to form.

THE WITNESS: Most applications would involve residual lubricants. There have been a couple of troubleshooting -- work that I've done for troubleshooting purposes to determine -- to try to solve a manufacturing issue, such as the fiber feeling sticky, for example, and trying to determine what could cause that.

BY MR. ANDERSON:

Q. Are you familiar with the -- strike that.

Are you familiar with the Johnson &

Johnson credo?

A. Yes.

Q. Do you pronounce it credo or credo?

A. Credo.

- - -

(A discussion off the record occurred.)

- - -

(Deposition Exhibit No. T-270, Johnson & Johnson Credo, 1 page, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. I'm going to hand you Plaintiff's T-270. I printed this off Johnson & Johnson's website.

Is that the credo that you're familiar with?

A. Yes. It's gone through a few iterations over the duration of my employment, but it's essentially the same.

Q. So since you became employed at Johnson & Johnson/Ethicon in 1979, there has always been a credo in some form in place?

A. There has been, yes.

Q. As you look at this one, is this what you believe to be the current version of the credo?
A. This appears to be current, yes.
Q. Even though it says "Johnson & Johnson" at the bottom, it applies to other companies owned or operated by Johnson & Johnson like Ethicon. Correct?
A. That is correct.
Q. So if we're talking about the Johnson & Johnson credo, we're also talking about the Ethicon credo. Correct?
A. Yes.
Q. And that's whether it's a Johnson & Johnson or Ethicon facility in the United States or at any other of its facilities worldwide. Correct?
A. I believe so, yes.
Q. This is actually on the wall, as soon as you come in to Johnson & Johnson. Correct?
A. It is.
Q. When you walk into your facilities in Somerville, is it on the wall there?
A. It's on at least one wall.
Q. When was the last time you read the credo?
A. I believe it was last year.

Q. Before your last deposition?
A. No. It was before, a credo survey.
Q. What is a credo survey?
A. At periodic times, Johnson & Johnson conducts surveys of its employees with respect -- which they call a credo survey. And they basically ask a number of questions that -- relating to the credo to get employee feedback.
Q. Is that sent out via e-mail or in what form of media is the survey conducted?
A. It's electronic. There's usually an e-mail notification along with a link.
Q. And do you follow that link in order to go through a series of questions that you answer?
A. Yes.
Q. Related to the credo?
A. Yes. Years ago, it used to be physical. In other words, they'd get the employees together and you'd actually fill it out by hand.
Q. How long have you been doing it electronically approximately?
MR. DAVIS: Object to the form.
THE WITNESS: I'm going to say maybe six to eight years.
BY MR. ANDERSON:

Q. Is it done at least once a year, this Johnson & Johnson credo survey?

A. I don't know if it's done at least once at year. It's done at most once a year.

Q. Is that an opportunity for employees of Johnson & Johnson/Ethicon to state whether or not they believe that the credo is being followed --

A. It is --

Q. -- or violated in some manner?

A. Yeah. It's an opportunity for the employees to express their opinions, not only on questions, but there are, at the end of the surveys, usually a comments section. So if they have anything specific they want to say, they may.

Q. So it's a way for employees to give feedback to management in terms of whether or not the employees feel that Johnson & Johnson is in fact following its credo. Correct?

A. Yes. It's an opportunity.

Q. If you look at that first -- those first two sentences, under "Our Credo," "We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality."

Did I read that correctly?
A. Yes.
Q. And do you believe that?
A. I do.
Q. Do you believe that your colleagues follow that credo?
MR. DAVIS: Object to the form.
THE WITNESS: In general, yes, I believe they do.
BY MR. ANDERSON:
Q. So one of the things that this particular part of the credo was saying is that the people who use our products, their safety must come first. Correct?
A. It doesn't say that specifically.
Q. Is that one of the fair characterizations of this first sentence or the -- and the second sentence, that in terms of patients, their health and safety must come first at Ethicon. Correct?
A. We're certainly concerned about that, but that's not what this document says.
Q. What's the primary concern at Ethicon and Johnson & Johnson? Would it be profits to shareholders or patient safety?

MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. Or are they equal?
MR. DAVIS: Object to the form.
THE WITNESS: That's basically a judgment call or an impression on my part. I don't know if I can really answer what upper management's primary goals are or what their relative priorities are, but I do believe that they follow the spirit of the credo in that we make products of high quality that are safe and efficacious, and since we are a private company, yeah, there is a -- there is some type of profit margin that's realized.
BY MR. ANDERSON:
Q. And I appreciate you answering that.
My question is, what comes first, patient safety or the business aspect of it, the profits, or are they equal in your mind after being an employee there for 34 years?
MR. DAVIS: Objection.
THE WITNESS: I can't comment on that. I can't comment on what priorities they assign. Certainly all those considerations are taken into account, but I have no idea what the relative priorities are.

BY MR. ANDERSON:

Q. In your mind, for your relative priorities as a 34-year employee, when you see this credo on the wall, in your mind, do you believe that patient safety comes first before profits or profits come before patient safety?

A. I don't look at it in that term.

Q. Well --

A. I don't assign a hierarchy or a priority.

Q. So in terms of your reading of this part of the credo, you don't have a feeling one way or another as to whether or not patient safety should come before profits of Johnson & Johnson/Ethicon. Is that your answer?

MR. DAVIS: Object to the form.

THE WITNESS: No. My answer is that I believe that Johnson & Johnson's products takes into account patient safety, that they're efficacious, that they're of high quality and that they are sold and there is a profit margin realized. I have no idea how high or how significant that profit margin is. And I don't have a concern as to what the relative priorities of those items are. All I know is that they're all taken into account

when a product is released.
BY MR. ANDERSON:
Q. You don't have a concern as to whether or not your company puts profits ahead of patient safety?
MR. DAVIS: Object to the form.
THE WITNESS: Repeat that question, please?
BY MR. ANDERSON:
Q. You just said, I don't have a concern as to which one comes first, so I'm trying to clarify --
A. No, no, I didn't say that.
Q. That's why I tried to clarify.
Is that what you're saying?
A. You're paraphrasing me. I said my concern -- I don't have a concern in terms of what priorities they assign. My -- I'm confident that the products that are released cover safety and efficacy, they're of high quality, and I do realize that they recognize a profit margin, although I have no idea what that is.
Q. So in reading back your answer, "I don't have a concern in terms of what priorities they" -- you mean upper level management? Who is

"they"?

A. I don't have a concern -- the -- well, you asked me about priorities. I don't know what the priorities are. And I'm not concerned about -- and I don't look at it in terms of a priority-type system. All of these features are taken into account when we release a product.

Q. So you don't have a concern as to whether or not the management of Johnson & Johnson and Ethicon puts profits before patient safety?

MR. DAVIS: Object to the form.

THE WITNESS: I'm confident that all of those factors are taken into account.

BY MR. ANDERSON:

Q. Do you believe that that would be a good part of the credo, to say that we put patient safety before profits at Johnson & Johnson?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I haven't been given an opportunity to author for the credo, and I don't feel I'm qualified to do that.

BY MR. ANDERSON:

Q. Well, now's your opportunity.

MR. DAVIS: Object to the form.

THE WITNESS: Well, I'm going to have

to pass on that opportunity, because I don't feel comfortable doing that.

BY MR. ANDERSON:

Q. Do you believe that a company who manufactures permanently implanted medical devices for a woman's pelvis should put patient safety before their profits?

MR. DAVIS: Object to the form.

THE WITNESS: I don't believe it has to come to a decision on that.

BY MR. ANDERSON:

Q. If there's a decision as to whether or not the company is going to make a profit but it will come at some risk of injury to the patient, do you have a feeling one way or another as to the -- whether the priority should be making that profit or making a safer product?

MR. DAVIS: Object to the form.

THE WITNESS: I don't believe that type of proposition really comes into play.

BY MR. ANDERSON:

Q. Let's assume it does. Let's assume Johnson & Johnson and Ethicon, your colleagues that you've worked with for 34 years, are in -- they're at a decision tree, at a crossroads. If we go this

way, it's going to be better for our profits, but it could hurt patient safety, but if we go this way, it could hurt the profits vis-à-vis our competitors, but it's going to make patients safer.

Which road should Johnson & Johnson and Ethicon take?

MR. DAVIS: Object to the form.

THE WITNESS: I'm inclined to believe that they would take the road that would ensure patient safety.

BY MR. ANDERSON:

Q. So is it your understanding that Johnson & Johnson's credo puts patient safety before corporate profits, or do you not have a feeling one way or another?

MR. DAVIS: Object to the form.

THE WITNESS: I believe they take a balanced approach to it.

BY MR. ANDERSON:

Q. A balanced approach, meaning?

A. They weigh -- they have to weigh all these factors.

Q. This is your opportunity to write this part of the credo.

Do you believe, being involved with

this company as long as you have, that your credo should be we put patient safety before profits always?

MR. DAVIS: Object to the form.

THE WITNESS: I don't have enough experience as a businessman or an owner/operator of a business, even this business, to make that decision on my own.

BY MR. ANDERSON:

Q. How about as a person in the community, as a consumer yourself, do you believe that companies should put patient safety ahead of corporate profit?

MR. DAVIS: Object to the form.

THE WITNESS: I believe that companies should be responsible for putting out safe products.

BY MR. ANDERSON:

Q. And do you believe -- that's not an answer to my question.

As a person in the community, as a consumer yourself, do you believe that companies should put patient safety ahead of corporate profits?

MR. DAVIS: Object to the form.

THE WITNESS: That still puts me in the role of operating a business. I'd have to -- to really look at that objectively, I'd have to look at myself as a business owner, and there are just a number of factors and considerations that I have no clue about, and, therefore, I'm just not capable of adequately answering that question.

BY MR. ANDERSON:

Q. I take it from time to time you've had to take medications in your life?

A. Yes.

Q. When you reach into your medicine cabinet and you take down a pill bottle, do you care whether or not the company who made that pharmaceutical put your safety ahead of their corporate profits?

MR. DAVIS: Object to the form.

THE WITNESS: I'm concerned about the product's safety and, therefore, I'll read the literature about it. And I'll consult with my physician and get his opinion as to how safe and efficacious the drug is for, you know, whatever ailment I'm taking it for, so -- but I don't make a -- I don't do a value proposition thought process on terms of, you know, profit versus safety. The

product is released. It has the -- meets certain guidelines, you know, it has to have some type of safety information on there to support it, so -- and then Johnson & Johnson I think is pretty responsible about the products it releases, so that combination of information is going to determine whether or not I feel safe taking that drug.

BY MR. ANDERSON:

Q. When you reach into that cabinet and you take that medication, do you expect that the company who made that was more concerned about your safety than they were about making a profit?

MR. DAVIS: Object to the form.

THE WITNESS: I don't think about that consideration when I take a pill off the shelf.

BY MR. ANDERSON:

Q. Think about it right now with me, if you would.

If you are taking a medication or you're going to have a medical device implanted in your body for the rest of your life, would you rather the company had put patient safety first and profits somewhere down below that or profits ahead of your safety?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Which way?

A. I'm concerned that the product is safe. The profit margin is whatever the company is going to get for it. If it's a good quality product, it may be -- it may very well be worth the profit margin the company asks for it.

Q. So if you were asked to write down this portion of the credo of profits versus safety, am I correct that you wouldn't write Johnson & Johnson should always put patient safety ahead of corporate profits?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Signed Dan Burkley.

You wouldn't write that?

MR. DAVIS: Object to the form.

THE WITNESS: I can't make a comment as to what I would write until I actually go and write that credo.

BY MR. ANDERSON:

Q. I'm asking you right now, as a 34-year employee of an international company that makes products worldwide, some of which will be permanently implanted in human beings, do you

believe that part of the credo, if you could write it, should say, we should always put patient safety ahead of corporate profits?

MR. DAVIS: Object to the form.

THE WITNESS: I would certainly write a statement about the product being safe, efficacious and of high quality, but I would not compare it or put any kind of qualifier in it with respect to profits.

BY MR. ANDERSON:

Q. If Johnson & Johnson and Ethicon make a profit on a product that is less safe for patients or consumers, or they can make another product that they're not going to make as good a profit on but it's going to be more safe, and they do equally the same thing, which should it use?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Which should it make?

MR. DAVIS: I'm sorry. Object to the form.

THE WITNESS: There are too many variables in that simple comparison that I would have to take into account besides the scenario -- besides the details of the scenario that you've

given me. And I can't make a judgment call on that.
BY MR. ANDERSON:
Q. If you look to the third paragraph, "We are responsible to the communities in which we live and work and to the world community as well."
Do you see that?
A. I do.
Q. Do you agree with that as a good rule for Ethicon and its employees?
A. Yes.
Q. "We must be good citizens -- support good works and charities and bear our fair share of taxes."
So if you as an employee of Ethicon and Johnson & Johnson are to be responsible to the communities in which you live and work as well as to the world community, don't you agree that you should have patient safety as your primary concern?
A. That paragraph doesn't really address patient safety.
Q. I'm asking you this question, though.
Based upon, "We are responsible to the communities in which we live and work and to the world community as well." Stop right there.
A. It has nothing to do with patient

safety.

MR. DAVIS: Wait a second. Object to the form.

BY MR. ANDERSON:

Q. Okay.

Your reading of that is what?

MR. DAVIS: Object to the form.

THE WITNESS: That we have -- the responsibilities that I believe that are meant in that with respect to the community in which we live and work would be such things as being environmentally friendly and being cognizant of environmental laws, being good citizens, support good works and charities, bear our fair share of taxes, in other words, we're responsible for paying our taxes, we contribute to worthy causes and that we're active and do good deeds in the community and encourage civic improvements, better health and education.

BY MR. ANDERSON:

Q. So other than Johnson & Johnson and Ethicon being a good citizen who is in tune with environmental concerns, taxes, charities and doing good deeds, do you believe that Ethicon and Johnson & Johnson is also responsible to the communities in

which you live to make sure that the products that you're making are as safe as possible without regard to corporate profit?

MR. DAVIS: Object to the form.

THE WITNESS: That might be covered in another section of the credo, but this particular section I believe does not have anything to do with patient safety.

BY MR. ANDERSON:

Q. I'm not asking about this particular section. You gave me your interpretation of it.

A. That's correct, my interpretation, yeah.

Q. My question was a follow-up to that.

A. Okay.

Q. Saying that in addition to the environment and taxes and charities, all of which are good things.

A. Right.

Q. Do you also believe that being a good citizen of our community, you and your fellow employees at Johnson & Johnson and Ethicon, in order to be good, responsible citizens in the community need to ensure that you put products on the market in which patient safety came before making a dollar?

MR. DAVIS: Object to the form.

THE WITNESS: I don't believe that consideration is part of this section of the credo, and it's -- you know, that would be addressed in another section of the credo. But as far as being responsible to communities and where we live, it's basically how this business interacts with the community and to, you know, the citizens and to the -- and its responsibilities to government, so...

BY MR. ANDERSON:

Q. Again, you're trying to interpret it from that section. And I'm not. My question is not is that what this section means.

My question is, do you believe as a 34-year employee --

A. Uh-huh.

Q. -- of Johnson & Johnson and Ethicon that you and your fellow employees in designing and manufacturing and selling products --

A. Uh-huh.

Q. -- to the members of your community, that your credo should say your patient safety comes before us making a dollar?

MR. DAVIS: Object to the form.

THE WITNESS: I --

BY MR. ANDERSON:

Q. Would you consider that being a good citizen pursuant to your credo, sir?

MR. DAVIS: Object to the form.

THE WITNESS: Again, you're asking me to write what the -- to put in what the credo says. There are too many other considerations that have to be weighed before I put in such a statement. And I'm not prepared to go through that. I don't have the means of doing that evaluation or the experience of doing that evaluation, so I'm not comfortable making that statement at this time. So I am confident that the company does keep safety and efficacy in mind with each of its products and that it's of high quality and that these are taken into account when we release our products into the community.

BY MR. ANDERSON:

Q. So as part of the community, if one of your neighbors comes up and says, I'm considering whether or not to have transvaginal mesh put into me manufactured by your company and I would like to know as a citizen of this community, you, Mr. Burkley, and as a citizen of this community, you as an employee of Johnson & Johnson and Ethicon, did

your company put my safety first or your corporate profits first, what are you going to tell that neighbor?

MR. DAVIS: Object to the form.

THE WITNESS: I can't answer that question.

BY MR. ANDERSON:

Q. Okay.

If you look at the last paragraph, "Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for."

Do you see that?

A. Yes.

Q. I'd like to focus on "mistakes paid for."

If Ethicon/Johnson & Johnson employees violate their credo and consumers of your products are injured, what should be the penalty to your company?

MR. DAVIS: Object to the form.

THE WITNESS: That's a pretty complicated question, and I am really not in a

position of knowledge or experience to answer that.
BY MR. ANDERSON:
Q. Do you agree that a company should never needlessly endanger the consumers of its products?
MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. Can we agree to that?
A. Repeat that, please?
Q. That a company should never needlessly endanger the safety and health of consumers of its products?
MR. DAVIS: Object to the form.
THE WITNESS: Well, I can't account for every type of business there is, but in general I would expect most businesses to do as you've indicated there, to not needlessly put -- I'm sorry, repeat that again?
BY MR. ANDERSON:
Q. Consumers.
A. Consumers.
Q. So you would agree with that principle, that companies should not -- strike that.
In general, companies should never needlessly endanger the consumers of its products.

Right?

A. Without knowing the specific nature of the business or what its consumers are, I would say in general, that would be a reasonable expectation. You know, but, again, I don't know the details of any particular company that you're talking about or how that could be extrapolated.

Q. Should Johnson & Johnson and Ethicon ever needlessly endanger the consumers of its products?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I would certainly hope not.

BY MR. ANDERSON:

Q. Would it be a good principle, even though it may not be the exact words in the credo, would it be a good principle for your company, Johnson & Johnson and Ethicon, to follow, we at Johnson & Johnson and Ethicon should never needlessly endanger the consumers of our products?

MR. DAVIS: Object to the form.

THE WITNESS: Again, I don't have experience as a business owner or operator. There are a lot more details involved that would need to be considered to make such a conclusion that I don't

have at hand, and I just don't feel qualified to make such a strong recommendation as that.

BY MR. ANDERSON:

Q. You believe that Johnson & Johnson and Ethicon should make products that are as safe as possible for the consumers who buy their products. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I guess that would depend on how safe safe can be at the expense of everything else, because you could extrapolate that to an extreme that, you know, may not make it viable as a product or even useful as a product.

BY MR. ANDERSON:

Q. Some products carry certain risks. Correct?

A. Some products do, yes.

Q. And some of Johnson & Johnson and Ethicon's products carry risk. Correct?

A. Yes.

Q. Is it ever okay for Johnson & Johnson to manufacture a product and to sell it to consumers that has needless risk?

MR. DAVIS: Object to form.

THE WITNESS: Again, that's a

scenario that has a number of variables that I'm unaware of, and consequently, I really can't make a qualified answer to that.

BY MR. ANDERSON:

Q. So just to make sure the jury understands, you, Dan Burkley, as a 34-year employee of Johnson & Johnson/Ethicon don't have an opinion as to whether or not your company should have an internal rule or principle that says we, Johnson & Johnson/Ethicon, should never needlessly endanger the patients who use our products?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. I just want to make sure I've got that right.

A. I don't know -- well, since you're asking my opinion, I don't believe that Johnson & Johnson does that to begin with. So, therefore, I don't see it as a requirement for a credo.

Q. There's certainly lots of different employees in your company. Correct?

A. Yeah.

Q. And different ones have different opinions as to whether or not a product should be put on the market or not. Correct?

A. I'm sure they do.

Q. Are you saying that one of the guiding principles of Ethicon and Johnson & Johnson should always be, when we're developing this, we should never expose patients to needless danger with our products.

Can we agree to that?

A. I'm not saying that that's --

MR. DAVIS: Wait, wait a second. Object to the form.

You can answer.

THE WITNESS: I'm not phrasing it the way you did. I don't -- I'm not saying that they have a guideline.

BY MR. ANDERSON:

Q. Should they?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Should Johnson & Johnson and Ethicon have a guideline that says, we should never needlessly endanger the consumers of our products?

MR. DAVIS: Object to the form.

THE WITNESS: Again, as a -- that would be a business decision. And again, I'm not a business owner or operator and don't have that kind

of experience to really explore all the ramifications of adopting such a guideline or not adopting such a guideline.

BY MR. ANDERSON:

Q. Do you care whether or not women who are implanted permanently with your transvaginal meshes made at Ethicon and Johnson & Johnson are exposed to needless dangers?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Do you not care?

A. Sure, I care.

Q. Well, if you care, don't you believe there should be an internal guiding principle at Johnson & Johnson that says, in making our transvaginal mesh products, we should never needlessly endanger the women in which they're going to be permanently implanted?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Should that be a guiding principle?

A. I believe that the way that Ethicon designs and develops its products takes the consideration of the safety and health of the patients and -- as well as the quality of the

product.

Q. And if Johnson & Johnson and Ethicon fail to do that and they manufacture a product that needlessly endangers the consumers of that product, don't you agree that those mistakes or those actions should be paid for?

MR. DAVIS: Object to the form.

THE WITNESS: Where it indicates mistakes are made, yes, I believe. I believe there's a responsibility to own up to that.

BY MR. ANDERSON:

Q. And if it's more than a mistake, if a decision is made by Johnson & Johnson/Ethicon to go for corporate profits over patient safety and they needlessly endanger the consumers of its products, they should pay for that. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That's a scenario that needs to be defined a lot further than what you've described as a generalization in order for me to make any kind of decision on that.

BY MR. ANDERSON:

Q. If Johnson & Johnson manufactures a product that is going to be permanently implanted into its consumers, and in manufacturing that they

were more concerned with business profits than they were the safety of those patients, thereby needlessly endangering these patients and causing them harm, shouldn't Johnson & Johnson and Ethicon own up to that and compensate those patients?

MR. DAVIS: Object to the form.

THE WITNESS: Without knowing more details about that, I can't make a comment about that.

BY MR. ANDERSON:

Q. If a company exposes you to needless harm, should they pay for that?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Let me give you that scenario again.

If you as a consumer of a product are put in needless harm -- strike that.

If you as a consumer of a product are harmed needlessly as a result of a product, do you believe that the manufacturer of that product should compensate you for your harms and losses?

MR. DAVIS: Object to the form.

THE WITNESS: I'd have to know more about the specific circumstances. I know certainly if it happened to me, I'd need to get as much

information as I could about that. If I felt that the company was responsible, sure, I would, you know, try to look for some kind of compensation.

BY MR. ANDERSON:

Q. For your harms and losses. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Again, it depends on the circumstances.

BY MR. ANDERSON:

Q. If Ethicon and Johnson & Johnson put profits before safety and they created transvaginal mesh products and needlessly endangered thousands of women, if those women suffer harm and injury, should Johnson & Johnson/Ethicon pay for their mistakes --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- pursuant to your credo?

MR. DAVIS: Object to the form, I'm sorry.

THE WITNESS: Well, the credo is a company-based philosophy.

BY MR. ANDERSON:

Q. Sure.

A. You know, the business will make whatever decisions it's going to make, you know,

with keeping the credo in mind. Its responsibilities to the community and, you know, as far as how it operates, it's going to follow the laws of the land as far as that goes, so -- but, again, your -- to make a judgment call on that, I'd need to know a lot more details in order to make that kind of decision.

Q. Forgetting the laws of the land for a minute, as a company -- strike that.

As a company that makes billions of dollars in profit per year -- strike that.

Johnson & Johnson and Ethicon makes billions of dollars in profits per year; is that correct?

MR. DAVIS: Object to the form.

THE WITNESS: I believe so, yes.

BY MR. ANDERSON:

Q. So let's work on that premise.

A company that makes billions of dollars in profit per year, if they needlessly endanger the consumers of their products and those consumers are injured, no matter what the law is, they should do the right thing and compensate those people for their harms and losses.

Would you agree with that, sir?

MR. DAVIS: Object to the form.

THE WITNESS: It will still depend on the specific nature and circumstances. There's a lot of details that that generalization covers that I'm not privy to and, you know, therefore, I'm just not -- I'm not qualified to really give a comment on that.

BY MR. ANDERSON:

Q. I'm not asking what you're privy to. I'm saying as someone who's been with this company for 34 years, do you believe it's the right thing to do for Johnson & Johnson and Ethicon, that if they expose women to needless dangers as a result of transvaginal mesh products, and these women are harmed, Johnson & Johnson and Ethicon should do the right thing and step up to compensate these women for their harms and losses? Do you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: Again, it's going to depend on the circumstances and just how much fault lays with the company.

BY MR. ANDERSON:

Q. They made a product in our scenario that needlessly endangered patients.

A. Yeah, but in --

MR. DAVIS: Wait. If that's a question, I object to the form.

MR. ANDERSON: I wasn't through.

THE WITNESS: Again, I don't --

MR. DAVIS: Oh, I'm sorry.

MR. ANDERSON: Quit interrupting me.

MR. DAVIS: Yeah. Make sure he gets his question off.

THE WITNESS: Okay, I'm sorry.

MR. ANDERSON: I sometimes pause. No problem. The tape's almost done, so -- how much time you got?

THE VIDEOGRAPHER: Three minutes.

MR. ANDERSON: Oh, three minutes. Okay.

BY MR. ANDERSON:

Q. So do you believe that it is a guiding principle of Johnson & Johnson/Ethicon that if they have needlessly endangered women's very lives with transvaginal mesh products, and these women are injured and harmed, that they should be compensated for those harms and injuries?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know if that's a guideline.

BY MR. ANDERSON:

Q. Should it be?

MR. DAVIS: Object to the form.

THE WITNESS: Again, I'm not in a position to make a business decision as to what guidelines the business should operate under.

BY MR. ANDERSON:

Q. If a company in the United States manufacturing a product needlessly endangers and harms the consumers of its products, do you believe that it should compensate those individuals for the harms and losses that they received?

MR. DAVIS: Object to the form.

THE WITNESS: It's going to depend on the details and circumstances of that incident.

BY MR. ANDERSON:

Q. So as a general principle, you can't agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: Not without knowing more details.

MR. ANDERSON: Okay. Why don't we take a break.

THE VIDEOGRAPHER: We're going off the record. The time is 10:45 a.m. This is the end

of Tape Number 1.

- - -

(A recess was taken from 10:45 a.m. to 11:01 a.m.)

- - -

THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 and Tape Number 2 of the deposition of Daniel Burkley. The time is 11:01 a.m.

BY MR. ANDERSON:

Q. I show you Plaintiff's Exhibit T-271.

- - -

(Deposition Exhibit No. T-271, "Our Ethical Code for the Conduct of Research and Development," 1 page, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. I also printed this off from the J&J website. "Our Ethical Code for the Conduct of Research and Development."

Have you ever seen this document before?

A. I think I've seen it once.

Q. When was that?

A. Probably about two or three years ago.

Q. Under what circumstances, please?

A. It was brought to my attention, so I took a look at it briefly.

Q. When you read it, did you agree with the principles contained in it?

A. Yes, I did.

Q. Do you follow the principles contained in it?

A. I do.

Q. Is one of the purposes of the credo, whether we're talking about the one we just spoke about or this R&D portion of it, is one of the primary purposes of that patient safety?

A. Patient safety is certainly a consideration. I don't know if it's paramount.

Q. Okay.

Under the "Preamble" of this document, Plaintiff's T-271, it says, "Our Ethical Code for the Conduct of Research and Development is intended to complement our credo--"

And "our credo" was the document we just looked at, T-270. Correct?

A. Yes.

Q. -- "by providing more specific standards of conduct and behavior for physicians, clinical research" assistants or "scientists and others who are responsible for medical aspects of research and development."

So --

And that's talking about physicians, research scientists and others responsible for medical aspects of R&D who are Ethicon and Johnson & Johnson employees. Correct? That's what it's referencing?

A. Yeah, clinical research scientists and others who are responsible for medical aspects of research, yes.

Q. Who are also employees of Johnson & Johnson and Ethicon. Right?

A. Yes, yes. That's correct.

Q. You would be contained within that -- those set of titles. Correct?

A. That I'm not too sure about. I'm not a clinical research scientist, and I'm certainly not responsible for medical aspects.

Q. Do you believe that Johnson & Johnson and Ethicon intends for you, Dan Burkley, as an employee, to follow this credo?

MR. DAVIS: Object to the form.

Ben, I only objected that time because you said "this credo."

MR. ANDERSON: That's a good point.

BY MR. ANDERSON:

Q. So right now we're going to reconcile -- can we call this the R&D credo for purposes of the record? Is that okay for you?

A. That's fine.

Q. So do you believe that Ethicon intends for all of its employees to follow this more specific standard of conduct for its employees?

A. No, considering they have a qualifier in there.

Q. So do you believe this applies to you?

A. Technically, no.

Q. Okay.

If you look at the second bullet point, "Our Ethical Code is intended to describe the principles that guide ethical decision-making to ensure the safe use of our products, and the best interests of our patients and their families, doctors, nurses and health care providers."

Do you believe that that is a good

rule for Johnson & Johnson and Ethicon to have internally, that ethical decisions should be made to ensure safety of its products for patients and their families?

A. Yes.

Q. Okay.

If you look under "Our Ethical Code."

"It is our fundamental responsibility to place the well-being of the patient first by appropriately balancing risks and benefits and to ensure the best interests of" physicians -- "of patients and physicians who use our products receive utmost consideration."

Do you see that?

A. I do.

Q. Do you believe that that principle stands for the code of conduct by Ethicon and Johnson & Johnson employees that, in everything that you do, you should put the well-being, the health and safety of patients first?

A. In everything we do. That sounds like an absolute statement, which is not included in here, so I'd have to say that that may be an overextrapolation.

Q. Do you believe that that is the

primary consideration, and that being the well-being, the health and safety of the patients coming first?

A. A primary -- yeah. I believe it's a primary consideration, yes.

Q. If you look down five bullet points, "It is our responsibility to ensure all Company-based, medically relevant product information is fair and balanced, accurate and comprehensive, to enable well-informed risk-benefit assessments about our products."

Do you see that?

A. I do.

Q. Do you agree with that principle?

A. I do agree with that principle.

Q. And what is your understanding of what fair and balanced means?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. In the context of how Johnson & Johnson defines it within its credos?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not quite sure how to interpret that without a specific example.

BY MR. ANDERSON:

Q. What's your general understanding of what fair and balanced means, providing fair and balanced information? Doesn't that mean you give the good with the bad?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. And you're accurate and thorough?

MR. DAVIS: Object to the form.

THE WITNESS: Well, that you -- you know, that you certainly -- I would interpret that to mean that you consider all the information that's available about it and it be fair in terms of explaining, you know, pros and cons, positives and negatives, you know, different aspects about it.

BY MR. ANDERSON:

Q. And as that's applied to you as a scientist, do you believe that fair and balanced means that if you undertake a study or an analysis, that you need to provide information that is accurate, comprehensive, fair and balanced?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I don't normally use the term "fair and balanced" with respect to studies or reports, but we certainly do include the other descriptives that you indicated being

accurate, factual and presenting all the data.
BY MR. ANDERSON:
Q. Well, for instance, let's just -- I'm trying to think of an example.
Let's say the FDA were to request information of your company, and you as a scientist were going to provide certain information, and they wanted to know about a potential complication or risk.
If you're involved in it as a scientist and you're trying to provide that information to a regulatory body like the FDA, you would want to provide both the positive and the negative, the pros and the cons of your particular research. Correct?
MR. DAVIS: Object to the form.
THE WITNESS: If they ask for my work, they would get the entire study, which would include all that, whatever information is in there.
BY MR. ANDERSON:
Q. Do you believe that a regulatory body has the right to assume that Johnson & Johnson and Ethicon will provide the good and the bad information that they have concerning a particular complication or potential problem with one of its

products?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Is that a good guiding principle?

MR. DAVIS: Object to the form.

THE WITNESS: Well, your question is putting me in the role of the regulatory body. I don't have regulatory experience. And it would be very speculative of me to try to assume what they would expect and not expect. So I -- it's not -- I don't feel it's an appropriate question to answer.

BY MR. ANDERSON:

Q. Do you think it's appropriate for a regulatory body like FDA to receive truthful and accurate and thorough information from scientists at Johnson & Johnson and Ethicon?

MR. DAVIS: Object to the form.

THE WITNESS: I believe that the FDA would expect to receive the information that they asked for.

BY MR. ANDERSON:

Q. Okay.

But if they have a question to ask of your company and you have data, should you provide accurate, truthful and thorough information to that

regulatory body?

MR. DAVIS: Object to the form.

THE WITNESS: They should provide a complete answer to their questions.

BY MR. ANDERSON:

Q. Should it be truthful and accurate?

A. Yes.

Q. Okay.

Do patients and doctors deserve the same level of respect as a regulatory body in that should patients and doctors who use Johnson & Johnson/Ethicon's products expect that Johnson & Johnson and Ethicon will provide truthful, accurate and full, thorough information about their products to them?

MR. DAVIS: Object to the form.

THE WITNESS: A customer is going to have different questions and/or concerns than a regulatory body would, so there isn't exactly a parallel between those two; but certainly if an end user had specific questions, you know, the company should attempt to give the end user adequate answers.

BY MR. ANDERSON:

Q. And by adequate, can we extend that

to say that it should be truthful and accurate and thorough information?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know any -- let's see. What am I trying to say?

In that particular role, which is not my role, I'm unclear as to what the company's responsibilities would be or what their guidelines should be in terms of dealing specifically with customer requests or requests for additional information, other than what's provided typically in the IFU provided for each product.

BY MR. ANDERSON:

Q. Okay.

Should the IFU contain truthful, accurate and fair and balanced information?

A. I believe so, yes.

Q. And if you as a scientist at Ethicon are asked to provide scientific data to, for example, a regulatory body, should it be truthful, accurate and thorough information?

MR. DAVIS: Object to the form.

THE WITNESS: Please repeat that question one more time.

BY MR. ANDERSON:

Q. Sure.

And if you as a scientist at Ethicon are asked to provide scientific data to, for example, a regulatory body, should it be truthful, accurate and thorough information?

MR. DAVIS: Object to the form.

THE WITNESS: As a scientist, I would certainly provide that information, but as a company, I believe there would be policies that the company would probably need to review that information before it was released.

BY MR. ANDERSON:

Q. Regulatory bodies who, like the FDA and other organizations around the world that are similar to FDA, one of the primary reasons they exist is to try to ensure patient safety of goods and products that are sold in its country, correct, over which it has regulatory authority?

A. Right. That's one of their concerns. I believe that.

Q. So if patient safety is a concern of a regulatory authority, would you agree with me that Johnson & Johnson and Ethicon have an obligation to provide truthful and accurate information to regulatory bodies about their products?

A. I don't know what their legal obligations are, but from an ethical point of view, yes, I believe they would.

Q. Okay.

Would you agree that a medical device manufacturer must not put their products on the market without knowing the risks involved --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- by using that product?

MR. DAVIS: I'm sorry, object to the form.

THE WITNESS: Again, that's a business decision. I'm not in that kind of position as a business owner or operator to really draw upon any experience or knowledge of requirements, obligations, to make those kinds of decisions.

BY MR. ANDERSON:

Q. Mr. Burkley, as a well educated, very bright principal engineer who's been employed by a multi-billion dollar medical device manufacturer for 34 years, do you believe that your company should know the risks involved with its products before they put them on the market and before United States citizens use them?

MR. DAVIS: Object to the form.

THE WITNESS: The company should be aware of risks associated with the products, yes.

BY MR. ANDERSON:

Q. Okay, thank you.

Do you believe that once problems are identified with regard to products that are already on the market by Johnson & Johnson, that your company should take appropriate steps to identify the problem, analyze the problem and come up with a solution?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Let me ask it a different way.

Do you feel that your company, Johnson & Johnson and Ethicon, has an obligation to patients and doctors after the product is put on the market to ensure that it is safe while being used?

MR. DAVIS: Object to the form.

THE WITNESS: The company is certainly concerned about the quality of the products that it sells and is diligent about quality improvement. So consequently, yes, they have concerns over the quality of the product and opportunities to improve quality.

BY MR. ANDERSON:

Q. In other words, you said a few minutes ago that you believe one of the fundamental principles of the credo and the R&D credo is patient safety.

Do you remember that?

A. That's a concern. I didn't say it was a guideline.

Q. Okay.

That's a concern?

A. Yes.

Q. It's not a fundamental priority?

A. It's a primary consideration, but it's not a guideline.

Q. So if patient safety is a primary consideration by Ethicon and Johnson & Johnson based in their credos, does that obligation to patient safety stop once the product is marketed?

MR. DAVIS: Object to the form.

THE WITNESS: No.

BY MR. ANDERSON:

Q. So Johnson & Johnson and Ethicon, pursuant to their credo, have an obligation to the consumers of its products that after the product is launched, they will continue to look at

complications or other risks to patients that may arise after the product is launched.

Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: State that one more time, please?

BY MR. ANDERSON:

Q. Sure.

So Johnson & Johnson and Ethicon, pursuant to their credo, have an obligation to the consumers of its products that after the product is launched, they will continue to look at complications or other risks to patients that may arise after the product is launched?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Do you agree to that?

A. Well, you're making an extrapolation that refers back to the original credo, whereas we were talking about this R&D credo document previously. And I believe that you're trying to draw one point from one document and apply it to the other.

Q. Okay. If that's your impression, it's wrong.

A. Okay.
Q. So let me see if I can do better.
A. Okay.
Q. You said that one of the primary considerations of Ethicon and Johnson & Johnson is patient safety. Correct?
A. With respect to the R&D --
Q. New question. New question.
A. Oh, I'm sorry.
Q. Okay.
Let's put the credo aside for a moment.
A. Okay.
Q. If that's confusing us, or we can come back to it.
But do you believe that one of the primary considerations at Johnson & Johnson and Ethicon should be patient safety?
A. It's one of the concerns they should have, yes.
Q. And that concern doesn't stop after the product is launched. Correct?
A. No. The concern does not stop, no.
Q. So in order to ensure a patient's safety after Johnson & Johnson and Ethicon's

products are launched, would you agree with me that it should continue to look at new patient complications, new risks associated with its products?

MR. DAVIS: Object to the form.

THE WITNESS: Well, it should certainly get more information about its products and how they're used.

BY MR. ANDERSON:

Q. Once problems are identified, should a medical device manufacturer take appropriate steps to do testing and analysis to see if those complications or risks could be eliminated or reduced?

MR. DAVIS: Object to the form.

THE WITNESS: If a complication has been identified, it should certainly be evaluated and confirmed and then some type of investigation done to determine if it's a quality issue or if there's a way to correct that deficiency or issue.

BY MR. ANDERSON:

Q. And here's what I'm getting at. Johnson & Johnson/Ethicon has thousands of employees worldwide. Correct?

A. Yes.

Q. You have scientists, you have doctors, you have engineers, all of the specialties required to research, develop, manufacture and sell medical devices. Correct?

A. They do.

Q. In fact, Johnson & Johnson and Ethicon are in the best position versus any other company or anyone else in the world to understand its products, to test its products and to analyze any potential complications with its products.

Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: Well, specific to its own products, yes, since it manufactures its products.

BY MR. ANDERSON:

Q. So if a complication --

If a potential complication or a risk with one of Johnson & Johnson and Ethicon's products arises, Johnson & Johnson and Ethicon are in the best position in order to identify that potential complication or patient risk, study it, analyze it and provide some sort of information as to whether they believe it is a true complication or a risk to a patient.

Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: Possibly. There are a number of other scenarios that could exist that might permit other end users or outside research firms to look at that and maybe get other information that Johnson & Johnson or Ethicon, you know, might not have. So, I mean, there are -- you know, there's -- it's conceivable other scenarios could be out there.

BY MR. ANDERSON:

Q. If Johnson & Johnson and Ethicon are made aware of complications related to its product or potential complications associated with its product, would you agree that your company has a duty and an obligation to reasonably determine the cause of the complications?

MR. DAVIS: Object to the form.

THE WITNESS: I believe it has a duty to investigate and confirm, and if after it's been confirmed, then to do some investigation or evaluation, you know, about it.

BY MR. ANDERSON:

Q. Would you agree that Johnson & Johnson and Ethicon must continue to do safety

testing, internal studies, to fund external studies, to review all the available new scientific literature that comes out and make any necessary design changes to the product in order to address patient safety issues that may arise during the life of that product?

MR. DAVIS: Object to the form.

THE WITNESS: Well, that goes to -- that's way beyond my area of expertise. And again, it's a business decision. And I'm not really qualified to address a question of such a broad -- basically such a broad question.

BY MR. ANDERSON:

Q. Well, do you believe that your company has an obligation to patients that over the life of that product, if new information is brought to Johnson & Johnson and Ethicon's attention, that there may be safety issues with your product, that Johnson & Johnson should do further testing or fund testing in order to look at that problem?

MR. DAVIS: Object to the form.

THE WITNESS: Well, Johnson & Johnson certainly has ways of collecting such information, such as product complaints or similar type things, and get as much information about these particular

products as possible. And they certainly do investigate those complaints. It's conceivable if it becomes a quality issue, then the company would then do some further investigation about that. But now I'm getting -- beyond that, I don't know exactly what they do or what they would be obligated to do.

BY MR. ANDERSON:

Q. On the last bullet point of the R&D credo, "It is our responsibility to challenge each other regarding medical and ethical concerns."

Do you agree with that?

A. As part of the Ethicon R&D code, yeah.

Q. Is that something that you regularly do, is challenge your colleagues and have other colleagues challenge one another at Johnson & Johnson and Ethicon regarding medical or ethical concerns with its products?

MR. DAVIS: Object to the form.

THE WITNESS: Well, considering I'm not a clinician and I'm not a medical doctor, it's kind of rare that I make those kinds of challenges.

BY MR. ANDERSON:

Q. If you saw an ethical concern at Johnson & Johnson or Ethicon, does the credo require

you to challenge those ethical concerns?

MR. DAVIS: Object to the form.

THE WITNESS: The credo itself does not specifically indicate that, but, I mean, in terms of a principle, certainly here in the ethical code for, you know, R&D, it indicates certainly that for its clinicians and other medical research scientists, you know, that they would bring these things up, so...

BY MR. ANDERSON:

Q. The last time you and I were together back in October, we had a discussion regarding the 2010 publication by Clave, et al. regarding the analysis of 100 explants and the potential degradation of the polypropylene that was seen in those explants that were used for either stress urinary incontinence or pelvic organ prolapse.

Do you remember us discussing that?

MR. DAVIS: Object to the form.

THE WITNESS: I do.

BY MR. ANDERSON:

Q. And do you recall that you told me that you were asked to be a part of a group of employees at Johnson & Johnson and Ethicon who looked at the Clave study and gave your impressions

as to what was contained within that study?

A. Yes.

Q. Since we last met in October, have there been any further meetings, discussions or communications regarding Ethicon/Johnson & Johnson's analysis of the Clave article?

A. No, there have not been.

MR. DAVIS: Note my objection to the form of the last question.

BY MR. ANDERSON:

Q. Were any studies, either internal or external, initiated since we last met in October with regard to addressing the potential for Ethicon's polypropylene meshes to degrade in the human body?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of any.

BY MR. ANDERSON:

Q. What were the circumstances under which Ethicon undertook this analysis of the Clave article?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. In other words, why did you do that?

A. I believe that regulatory felt that

it would be worthwhile to issue a response to the article.

Q. Why did regulatory feel that you should issue a response -- sorry.

Why did regulatory at Johnson & Johnson feel that it would be worthwhile to issue a response to the Clave article?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Your understanding?

MR. DAVIS: Object to the form.

THE WITNESS: There were aspects about the study that they felt needed commenting on to offer an alternative viewpoint.

BY MR. ANDERSON:

Q. To offer an alternative viewpoint to whom? The world at large, through scientific literature, to doctors, to patients? Who are you responding to?

MR. DAVIS: Object to the form.

THE WITNESS: The same audience of people that would have read the Clave article.

BY MR. ANDERSON:

Q. Were you aware, Mr. Burkley, that it was actually the United Kingdom regulatory agency

MHRA who requested information from Ethicon and Johnson & Johnson regarding its meshes and whether or not they may degrade or contract as was set forth in the Clave article?

MR. DAVIS: Object to the form.

THE WITNESS: No, I was not aware of that.

BY MR. ANDERSON:

Q. So no one told you that the reason they were asking you to provide your analysis and your opinion of the Clave article was to respond to a foreign regulatory body who had requested this information from Ethicon and Johnson & Johnson?

MR. DAVIS: Object to the form.

THE WITNESS: I did not have such information.

BY MR. ANDERSON:

Q. You said that you had in-person meetings as well as many e-mail exchanges regarding this analysis of the Clave article. That's what you told me at the last deposition.

A. Yes.

Q. Do you remember that?

A. Yes.

Q. So none of these meetings and none of

those communications, you're telling the jury you had no idea that a foreign regulatory authority had actually asked for Johnson & Johnson's response to the Clave article?

A. That's correct. I am not aware of that.

MR. ANDERSON: Plaintiff's Exhibit T-272.

- - -

(Deposition Exhibit No. T-272, E-mail chain, top one dated 01 Mar 2012, Bates stamped ETH.MESH.07226377 through ETH.MESH.07226379, was marked for identification.)

- - -

MR. ANDERSON: Last four Bates are 6377.

BY MR. ANDERSON:

Q. Have you ever heard of the MHRA?

A. No, I'm not familiar with that.

Q. If I tell you that the MHRA is similar to the FDA division of pharmaceuticals and medical device regulation, do you have any reason to dispute that with me today?

A. I'd probably want a confirmation of

it.

Q. For purposes of the deposition, I want you to assume with me that the MHRA is a regulatory agency in the UK that regulates the medical devices and other products sold in the UK in order to address patient safety as one of its priorities. Okay?

A. Okay.

Q. If you look at the second page of this e-mail, you'll see that in the middle of the page, it says "From: Clare.Huntington@mhra.gsi.gov.uk."

Do you see that?

A. I do.

Q. It was sent on January 26, 2012, and the subject was "Polypropylene mesh." Correct?

A. Yes.

Q. And if you look down below, it says, "Study_of_100_explants.pdf."

And we know that the Clave article is -- was a study of 100 explants. Correct?

A. Yes.

Q. And it is being sent to Mark.

"Dear Mark, Please find attached a paper suggesting that Polypropylene used in vaginal

meshes is not inert. Please could you provide me with your comments on this issue and also tell me about any testing you have carried out to show that the meshes used do not shrink."

Do you see that?

A. I do.

Q. You will recall that part of the Clave article talked about the degradation of both low weight and heavyweight -- lightweight and heavyweight polypropylene fibers. Correct?

A. Yes.

Q. It also talked about the meshes can contract or shrink in the human body. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I believe so, yes.

BY MR. ANDERSON:

Q. And it also offered that it was the first study to look at explants of polymer meshes in the pelvic floor to determine whether or not meshes degrade in a woman's body.

Do you recall that?

MR. DAVIS: Object to the form.

THE WITNESS: I believe -- yes, I believe that statement was made by the article, yes.

BY MR. ANDERSON:

Q. And that their conclusion was that they were not inert and that they actually -- strike that.

And the conclusion in the Clave article was that based upon their analysis of these explanted meshes, that polypropylene meshes do in fact degrade and are not inert.

Do you recall that?

MR. DAVIS: Object to the form.

THE WITNESS: I -- yes.

BY MR. ANDERSON:

Q. So if you look up above that, you see that there is an e-mail sent the next day from Complaints at Ethicon GB, which would be Great Britain. Correct?

A. Yes.

Q. And it's sent to various individuals, and it says, "Dear Melissa and Cary, See below and attached from the MHRA.

"I have also attached my response to Ms. Huntington.

"I haven't entered this as a complaint but if you need me to enter anything, just please ask?

"Can you provide me with a response?

"Many thanks, Marjorie."

So what we're seeing here is people within Ethicon, both in Great Britain and the United States, sharing this e-mail from the MHRA and looking for a response. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. And if you turn to the next page, three days later another e-mail is sent with the same subject line, and it says, "Dan and Brian," and that's Dan Lamont and Brian Kanerviko, "Please see the e-mail below with a request from MHRA regarding pelvic mesh. Brian, who from your team will take lead on helping with this from an RA" -- that would be regulatory affairs. Correct?

A. Yes.

Q. -- "perspective?

"Thank you! Melissa."

And that's on February 14th.

And then if you look up above from Laura Vellucci, there's a jump between February and March here, and we're going to get to some of those e-mails in a minute.

But it says, "As per our

conversation...I am" sending "the original request from the MHRA to comment on the issue: polypropylene mesh used in vaginal repair may not be inert."

Do you see that?

A. Yes.

Q. And you're copied on this e-mail -- oh, you're in the -- you're sent this e-mail as well. Correct?

A. Yes, I am.

Q. It says, "I am copying Dan and John as you have identified them as resources for the needed information. Sandy has provided a response on our testing to show that meshes used do not shrink."

Even though polypropylene itself doesn't shrink, you know, don't you, Mr. Burkley, that there's abundant evidence in -- both within Ethicon as well as in the literature outside of Ethicon that surgical meshes do have wound contraction causing the area of the mesh to shrink or contract. You know that. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm aware of articles that state that, yes.

BY MR. ANDERSON:

Q. And that's the --

That's known within Ethicon, that polypropylene meshes can shrink from 30 to 40 percent of their surface area due to normal wound healing and contraction. You know that. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know if they can contract to the extent that you just described, but I've heard of that, that they can contract.

BY MR. ANDERSON:

Q. So to provide an answer back to a regulatory body in the United Kingdom whose purpose is to try to ensure patient safety, to just say that our testing shows that meshes do not shrink, that's not a fair and balanced response. Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: I can't comment on that. It depends on how you define "shrink."

BY MR. ANDERSON:

Q. Well, when a regulatory body is asking the manufacturer for information and that manufacturer has information showing that mesh shrinkage and mesh contraction are words that are

used virtually interchangeable -- strike that. Let me ask you.

You understand that mesh contraction and mesh shrinkage are terms that are used in common vernacular in your industry somewhat interchangeably. You know that. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: They could be, but shrink could still have multiple definitions.

BY MR. ANDERSON:

Q. Was that, the fact that shrink could have multiple definitions, sent back to the MHRA to say what is it that you're asking us, because shrink could have multiple definitions? Was that sent?

MR. DAVIS: Object to the form.

THE WITNESS: I have no idea what the communication was to the MHRA.

BY MR. ANDERSON:

Q. We'll go through this and we'll find out whether or not --

A. Okay.

Q. -- your company just said our meshes don't shrink or can you explain to us what you mean by shrink, because you were -- strike that. New question.

You were aware as of March 2012, weren't you, Mr. Burkley, that mesh contraction occurred in polypropylene meshes manufactured by Johnson & Johnson/Ethicon? You were aware of that?

MR. DAVIS: Object to the form.

THE WITNESS: I have heard of articles stating that. How factual that was, I don't know.

BY MR. ANDERSON:

Q. And the article -- sorry.

A. From an analytical chemist's point of view, shrink could have a different meaning than what's used in a clinical application. So it's not clear which applications the term is being used at.

Q. As part of this -- we'll get to your part.

You were aware as of March 2012 that Ethicon's own consultants had published in the peer-reviewed literature that there is mesh contraction of all polypropylene meshes somewhere between 30 and 40 percent. You were aware of that at this time, were you not?

MR. DAVIS: Object to the form.

THE WITNESS: I was made aware of that during the deposition in October.

BY MR. ANDERSON:

Q. Were you aware of that at this time?

A. No.

Q. Were you asked to provide information as part of this analytical process in providing a response to the UK regulatory body about contraction? Okay? Were you asked to provide your response regarding whether or not your meshes contract or shrink?

MR. DAVIS: Object to the form.

THE WITNESS: No, my -- I was asked to comment on the SEM images.

BY MR. ANDERSON:

Q. So your role was more in the degradation rather than the contraction or shrinkage?

A. Well, basically to comment on the SEM images.

Q. It says, "It would be great if the information you are collecting and the data that Sandy has provided can be tied together so that we can present a complete picture of our understanding of the properties of polypropylene mesh and its appropriateness for use in vaginal mesh products."

"A complete picture of our

understanding of the properties of polypropylene mesh," do you see that?

A. Yes.

Q. If Ethicon was aware in March of 2012 that it was in the scientific literature that mesh contraction or mesh shrinkage can occur at 30, 40 percent but it tells this regulatory body our meshes do not shrink, that's not presenting a complete picture of Ethicon's understanding of the properties of polypropylene mesh, is it, sir?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I can't comment on what Sandy means by mesh does not shrink or do not -- the meshes used do not shrink. And I would need -- you know, you would have to ask her viewpoint in terms of what she means by that statement relative to your statement about contractures.

BY MR. ANDERSON:

Q. If Ethicon and Johnson & Johnson wanted to provide a complete picture of its understanding of the properties of polypropylene mesh with regard to mesh shrinkage, if it was going to follow its credo, it would have provided the literature and the testing of which it was aware

showing that there's mesh contraction or mesh shrinkage of up to 30 to 40 percent.

Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: If it had that data, that would certainly be part of the complete picture.

BY MR. ANDERSON:

Q. Right.

And if it had that data and did not provide a complete picture, that's a violation of its own credo. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That's a judgment call on the credo, and I'm not in a position to make a judgment call on that.

BY MR. ANDERSON:

Q. Let's go back to the credo.

It says, "It is our" responsible -- "responsibility to ensure all Company-based" or "medically relevant product information is fair and balanced, accurate and comprehensive, to enable well-informed risk-benefit assessments about our products."

When a regulatory body from the

United Kingdom is asking about the mesh shrinkage of your product, in order to follow your own credo at Johnson & Johnson and Ethicon to provide fair, balanced, accurate and comprehensive information and to present a complete picture of the understanding of the properties of polypropylene, you had an obligation and a duty both internally and to this regulatory body to ensure that you made them aware of 30 to 40 percent mesh contraction or mesh shrinkage of your products. Agreed?

MR. DAVIS: Object to the form.

THE WITNESS: The inquiry is actually made about the article. It's not made about this contracture to 30 or 40 percent.

BY MR. ANDERSON:

Q. Let's go back to the initial request, Mr. Burkley --

A. Yeah.

Q. -- from Clare Huntington.

A. Okay.

Q. She says, "Please could you provide me with your comments on this issue and also tell me about any testing you've carried out to show that the meshes used do not shrink."

Do you see that?

A. Yes.

Q. And if you had testing carried out either internally or externally through consultants, published in the worldwide peer-reviewed literature that said polypropylene meshes shrink from 30 to 40 percent, in keeping with your credo and in just doing the right thing, you should have told the MHRA that you're aware of mesh contraction or mesh shrinkage of 30 to 40 percent.

Do you agree?

MR. DAVIS: Object to the form.

THE WITNESS: I can't comment on who generated the data that included the contraction from 30 to 40 percent. I don't know if that's an internal study or an external study. This statement is asking for any testing that you've carried out to show the meshes do not shrink. That would fall under Sandy's area of responsibility, and it indicates that she has provided a response on our testing that show that meshes do not shrink. I don't know how complete or incomplete that is, and I really can't comment any further about it.

BY MR. ANDERSON:

Q. Well, I'm going to ask you to comment further about it, because it's one thing just to

answer the question and only answer the question. It's another to provide full and accurate information, even if it wasn't the exact specific technical question, wouldn't you agree?

MR. DAVIS: Object to the form.

THE WITNESS: In principle. In principle, I would agree with that.

BY MR. ANDERSON:

Q. And if as of March of 2012 Ethicon had internal PowerPoints and internal studies showing that they were aware that all of their polypropylene meshes shrink, that information should have been provided to Mrs. Huntington at the MHRA.

Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: I can't comment on that. I personally don't know if such information was available. It's outside my area of expertise and I just can't comment any further about it.

BY MR. ANDERSON:

Q. Well, if you're in this --

They've asked you, you said there was a series of meetings, there was e-mail communications back in March of 2012 about providing the response to the Clave article. Correct?

A. Yes, yes.

Q. If in the course of those meetings it came up that Ms. Huntington has said that she would like to know if we have any studies about mesh shrinkage, if your company had internal documents showing that they were aware of mesh shrinkage, would you agree with me, sir, that those should have been provided?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Or that information should have been provided to this regulatory person?

MR. DAVIS: Object to the form.

THE WITNESS: I can't make a comment on that. I don't know what information was there. I don't know what information was available. And I don't know how it would all be put together to present this, quote, complete picture.

BY MR. ANDERSON:

Q. But that is my point, is if the information was available to Johnson & Johnson and Ethicon, when this woman made this response, as part of this team, wouldn't you believe that this should be provided to this woman --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- whose job, at least in part, is ensuring patient safety, women's safety and well-being in the UK?

MR. DAVIS: Object to the form.

THE WITNESS: Again, that's a business decision that would be made by the regulatory affairs representative.

BY MR. ANDERSON:

Q. I'm not talking about the business decision. I'm talking about a women's health decision. We discussed a few minutes ago that a regulatory body, part of what they do is try to ensure patient safety.

Now that you are aware -- strike that.

As part of this team, if you knew that Ethicon had internal documents and was aware of external studies by its own consultants showing mesh contraction, don't you believe that women's health dictated that you provide this information to this regulatory body?

MR. DAVIS: Object to the form.

THE WITNESS: That information, if it's available, should certainly be consulted and

weighed in along with all the other data and information that we have in order to address the request about asking for any other information.

BY MR. ANDERSON:

Q. Well, how about instead of just consulting the information and weighing the information, why not just turn it over to the regulatory agency? That's my question.

MR. DAVIS: Object to the form.

THE WITNESS: That's not what was asked.

BY MR. ANDERSON:

Q. Okay. And that was the point we got to a few minutes ago.

And that is, you can either do a technical reading of, well, that's not exactly what she was asking, or you could say, this woman is asking from a regulatory body what we know about our mesh shrinkage, what testing's been done.

Don't you believe that women's health is important enough for you guys to look internally to see what documents you had, what studies you had, and to look at the scientific literature and to provide that information to her?

MR. DAVIS: Object to the form.

THE WITNESS: We were certainly obligated to look at whatever information we had available and offer basically -- as they said here, provide comments on this issue and results of -- let's see. And tell me about any testing that's been carried out. So that's what should be addressed.

BY MR. ANDERSON:

Q. And it was addressed.

And instead of providing that information, of which your company, a multi-billion dollar manufacturer of medical devices, and in particular these devices, that's what you were obligated to tell her. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm sorry, repeat that again, please?

BY MR. ANDERSON:

Q. Instead of providing that information regarding mesh shrinkage and mesh contraction of which your company was aware, your response simply was our meshes don't shrink. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know what the response was. I have -- it indicates here that she

has a response to show that meshes used do not shrink. I don't know the details of that report and whether or not it includes any of the information that you've cited -- that you've mentioned earlier, so I'm really not -- that's not my area of expertise and I really can't comment on what type of clinical information was provided.

BY MR. ANDERSON:

Q. You were asked to be a member of a team that had a response to the Clave article. Correct?

A. That is correct.

Q. As we've looked at these e-mails now, now you understand that the reason for this response was because of a request by a regulatory body in the UK. Correct?

A. I do, yes.

Q. And part of the reason that regulatory body exists is to protect patient safety. Correct?

A. Yes, that's one of the reasons.

Q. And if what they're trying to do is protect patient safety, and in particular women's safety and their health, shouldn't your company provide the information that it has regarding

shrinkage and contracture of meshes?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know the answer to that question. There's a lot of factors involved in terms of providing the information, and I'm not -- I'm only one part of that team. And again, I don't know all the information that was available and I don't know how much of that information was used in the response.

BY MR. ANDERSON:

Q. Is that okay for Johnson & Johnson and Ethicon, when asked to comment on an article that says that its polypropylene meshes may degrade in a woman's pelvis, is it appropriate not to provide all the information you have on that issue?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know. All the information would have to be reviewed and evaluated to see how much is applicable to the question.

BY MR. ANDERSON:

Q. Okay.

Well, now that we've talked about this today, do you intend to go back to your colleagues and -- I'm looking at the ethical R&D credo.

Do you intend to leave our deposition and challenge your colleagues regarding any ethical concerns they may be if in fact they didn't provide the information that they have regarding mesh shrinkage and contracture to this woman from a regulatory body seeking that information?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know for a fact they have not reported all the information. I don't know enough details to make a judgment call whether or not an ethical issue has been violated or whether one's even up to be challenged.

BY MR. ANDERSON:

Q. Are you proud of being a Johnson & Johnson and Ethicon employee?

A. Yeah, I am.

Q. So if you're proud of being an employee of this company that provides products that are going to be permanently implanted in women, ethically are you going to leave here as a scientist and a proud employee and ask your colleagues whether or not all of the information was provided to this regulatory agency when it was asked?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I'm aware of

polypropylene products, both sutures and meshes, have had at least 40 years clinical experience as being nonabsorbable sutures. And, you know, so I'm pretty comfortable with Prolene as a nonabsorbable material. Again, I don't know the specifics about what data was available and what wasn't available, but I do have confidence in my colleagues, both from the clinical and preclinical and regulatory affairs, that, you know, they're the right people to make -- you know, to review that data and determine what should be reported to the MHRA.

BY MR. ANDERSON:

Q. So you're not going to go say anything after this deposition to your colleagues about whether or not they should provide more information on mesh shrinkage and mesh contracture to this regulatory body, are you?

A. No. And I probably shouldn't do that for legal reasons, since there's current trials and I haven't talked to my -- any of my colleagues about any of this.

Q. Forget the legal reasons, what about the patient safety reasons. Let's talk about that for a minute.

Isn't women's -- new question.

Isn't women's health important enough that if you have information that you could provide to a regulatory body of which you're aware regarding degradation or shrinkage of your meshes, that you provide that to the regulatory body?

MR. DAVIS: Object to the form.

THE WITNESS: That's -- again, that's -- I'm not a -- I'm not in preclinical, I'm not a clinician, that's not my area of expertise. And all I know is that whatever information I do have should be provided to, you know, those experts within my company to use as appropriate for responding to regulatory agencies.

BY MR. ANDERSON:

Q. You said you had 40 years of experience with Prolene sutures, therefore, you had a certain confidence level. Correct?

A. Well, Prolene itself has had 40 years of clinical experience, so I'm pretty confident in the Prolene line of products.

Q. Right.

And the Clave article had both Prolene and Prolene Soft in it, didn't it?

A. It did.

Q. So you told us a little while ago in

the deposition that in 34 years at the company, you're only aware of one degradation study that was done 25 -- 28 years ago that was in a dog's heart.

Do you remember that testimony?

A. Yes, I do.

Q. So your company hadn't even done any degradation studies at the time Clave came out. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Well, it's a nonabsorbable material, and the clinical data that was available supported that.

BY MR. ANDERSON:

Q. Yes.

But now you have an article with 100 explants where it shows that polypropylene mesh that had been extracted and excised from women's pelvises showed that there was in fact degradation. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know -- well, I don't know for sure if that was degradation. There's certainly some evidence supporting that there may be some surface sites that are showing the initial signs of degradation.

BY MR. ANDERSON:

Q. And if it's showing the initial signs of degradation that supported their conclusion that polypropylene is not inert, why didn't your company do any degradation studies --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- after that?

A. I'm not convinced that polypropylene is not inert.

Q. And as a scientist, there's the thing called the scientific method. Correct?

A. Sure.

Q. You have a theory, and then you work to see if you can prove that theory. Correct?

A. Yeah.

Q. So if your theory is I'm not convinced that it cracks, where is your proof that it doesn't? What study has Ethicon done regarding explanted mesh from a woman's pelvis where you could actually look at degradation?

A. Well, considering that Prolene mesh is made out of Prolene fiber, you could still go back to suture studies, which is why -- you know, and again, there's 40 year -- 40-plus years of history as -- for -- of polypropylene being used as

a nonabsorbable suture material.

Q. The only one that you're aware of that Ethicon actually did was a seven-year dog study from the heart.

So what I'm asking you is, when you were made aware of Clave's study, why didn't Ethicon or Johnson & Johnson -- strike that?

Johnson & Johnson/Ethicon did not do any degradation study after Clave came out to either confirm or refute those findings, did it?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I'm not aware of any degradation studies. That doesn't mean that none were done.

BY MR. ANDERSON:

Q. When you leave the deposition today, are you going to go ask your colleagues whether or not any degradation studies have been done since your seven-year dog study back in the '80s?

MR. DAVIS: Object to the form.

THE WITNESS: Not until after the litigation issues have been resolved.

BY MR. ANDERSON:

Q. Why not?

A. Because there are legal implications.

Q. What's more important, legal implications or making sure that women don't have degraded polypropylene in their pelvises?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That's my question.

What's more important, the legal ramifications for your company of asking your colleagues if they've done degradation studies or letting -- or finding out whether or not the polypropylene that are in women's pelvises permanently implanted actually degrade?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Which one is more important?

A. Well, I'm pretty confident that the polypropylene itself does not degrade to any significant degree, so the risk I believe is minimal.

Q. That's not the answer to my question.

My question, you said that there's legal implications if you go and ask your colleagues if they've done any degradation studies since the '80s and certainly since this Clave article came out in 2010 and since you were asked to be on a

committee or a group of people in 2012 that looked at this degradation issue in response to a foreign regulatory body's request.

And so my question is, are you that worried about legal implications that you won't ask your colleagues about this, when in the balance is degraded polypropylene in a woman's pelvis?

MR. DAVIS: Object to the form.

THE WITNESS: No, but I'm willing to respect the possible legal risks involved, and I'm confident that the people that are involved in those studies, whether they be in the clinical or preclinical area, you know, are certainly going to be asked that information with respect to any investigations from, you know, as part of this litigation. So it's -- I'm sure that information is going to come out if it does exist.

BY MR. ANDERSON:

Q. What do you mean by that, I'm sure that information is going to come out if it exists?

A. Right. As I said before, I don't know if there were degradation studies initiated, to my knowledge.

Q. Okay.

A. But if I would -- you know, but I'm

assuming that if such studies were done, they would have been organized either under preclinical or clinical.

Q. And then you see in this exhibit, the last couple of sentences, after it says that we are going to "present a complete picture of our understanding of the properties of polypropylene mesh and its appropriateness for use in vaginal mesh products. At the end, we can add in Piet's comments from a clinical perspective as well. The response will be a work of art!"

Would the response be a work of art if it doesn't complete -- if it doesn't give the complete picture?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. And you know what I mean by this? It's not an appropriate complete picture if you don't provide the information that you have available to you that's relevant to the issues of degradation and shrinkage. That's not much of a work of art, is it, sir?

MR. DAVIS: Object to the form.

THE WITNESS: I can't comment on that. That's Laura's comment. I don't know what

she means by that.
BY MR. ANDERSON:
Q. Well, then let's take it out of the context of a work of art.
It's not a good piece of work by Ethicon and Johnson & Johnson if somebody charged with patient safety in the UK is asking you for information about contraction and shrinkage and you don't provide all the information you have. That's not good work?
MR. DAVIS: Object to the form.
THE WITNESS: The response may not require every last piece of work.
BY MR. ANDERSON:
Q. I didn't ask about every last piece of work.
A. You said all.
Q. Yeah.
If you have relevant information to this issue to present the complete picture --
A. Right.
Q. -- and you have your own internal documents at Johnson & Johnson/Ethicon saying, we are aware of mesh shrinkage and mesh contraction of 30 to 50 percent of our meshes, if you don't provide

that to the UK, it's not a complete picture and it's certainly not a work of art. Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know the value of that information with respect to answering the questions from the MHRA. That would be the responsibility of the preclinical or clinical representatives.

BY MR. ANDERSON:

Q. Let's just use common sense, like being a scientist and being an employee of a company that you say you're proud to work for.

If a regulatory body read this Clave article and they sent a direct request to your company saying can you provide me with any testing that you have on this shrinkage and respond to this article, the right thing to do would be to look and see if you have that information, and if you have it, provide it to them, regarding shrinkage and contraction of your polypropylene meshes. Right?

MR. DAVIS: Object to the form.

THE WITNESS: It depends on the circumstances and the details of the request.

BY MR. ANDERSON:

Q. The circumstances and the details are that a regulatory body charged with patient safety, and in this case women's safety, is asking your company for this information about mesh shrinkage and mesh contraction. And you are in a group that is charged with doing that. That's the backdrop. That's the context.

So my question in that context is, if someone were to put a stack of documents in front of you that had scientific literature done by your consultants and internal PowerPoints and other documents indicating that people at Johnson & Johnson and Ethicon charged with responsibility for patient safety and safe product design have said that they're aware of 30 to 40 percent contraction and shrinkage, if you're in that room and you had those documents, you, Dan Burkley, would you say, I've seen the response, this is a regulatory body, let's provide those to her? Or would you say, that's a business decision, that's up to you guys, I wash my hands of it, I don't want to be involved in that? Which way would you go?

MR. DAVIS: Object to the form.

THE WITNESS: I would go and review the data, each piece, see which ones were

appropriate for the response. It's possible that there's data that may be inconsequential or not directly related to what the MHRA has requested. So consequently, it wouldn't -- it may not be necessary to include it. But again, I'm not -- you know, this -- that information that you're asking for is either the clinical or preclinical data, and I'm not the one that's appropriate to make a judgment call as to which articles or which data should be included in the response.

BY MR. ANDERSON:

Q. Well, there was some -- there was certainly nothing that prevented you or your team in providing this response to her, nothing that prevented you from saying, here's our information. This information over here is of what we consider to be limited value, but it may be important to your decision, this we think is of greater value, and let her make the decision as to whether or not that information is important rather than you making the decision as to whether or not it was important, as Ethicon and Johnson & Johnson? Nothing prevented you from doing that?

MR. DAVIS: Object to the form. Object to the form.

THE WITNESS: Well, it would certainly be -- you know, the company would certainly reserve the right in terms of how it wishes to do that. But if it wants to take that information and you know, review it internally before it releases it, I mean, it certainly has that right to do that.

BY MR. ANDERSON:

Q. To your knowledge and as you sit here today, this team that you were asked to be a part of in March of 2012 to respond to the Clave article never provided any documents or information concerning mesh shrinkage or mesh contraction other than to say our meshes don't shrink.

Is that your understanding as you sit here today?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of what information the preclinical or clinical representatives provided.

BY MR. ANDERSON:

Q. Why are you limiting it to preclinical and clinical? I don't understand why you keep going to that.

A. Well --

Q. You're an engineer, and so I'm asking you as part of the team, as you sit here today -- so let me reask my question.

A. Sure.

Q. You as an engineer who was invited to be on this team because of your expertise --

A. Right. In analytical chemistry and scanning electron microscopy.

Q. Right.

You're not aware of any information that was provided by this team to the MHRA concerning degradation and shrinkage other than to say our meshes don't shrink. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of what information was provided by the clinical or preclinical representatives that would address that.

BY MR. ANDERSON:

Q. And if Ethicon/Johnson & Johnson had employees and documents within its organization that do believe that their meshes in fact shrink and suffer contraction, do you as a scientist and a 43-year employee believe that that information should have been provided to the MHRA in response to this request?

MR. DAVIS: Object to the form.

THE WITNESS: That depends on the request and the circumstances.

BY MR. ANDERSON:

Q. Well, we've gone through the request and the circumstances time and again. The request and the circumstances are this. The Clave article came out, the regulatory body in the UK asked your company for any testing they have on shrinking meshes. That's the context. That's the basis under which it was asked. You formed a committee under that basis.

A. We did.

Q. And my question is, when they were asked the question, what testing do you have and please respond as to whether your meshes shrink, this group, this company, did not provide any data to your knowledge or documents concerning anyone's belief in the company that their meshes shrink or contract?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of any.

Now, it indicates here that Sandy has provided a response in her testing to show that meshes do not shrink. I don't know the details of that.

MR. ANDERSON: Plaintiff's Exhibit T-273.

- - -

(Deposition Exhibit No. T-273, E-mail chain, top one dated 29 Feb 2012, Bates stamped ETH.MESH.04038180 and ETH.MESH.04038181, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. Last four Bates 8180.

An e-mail that will start in the middle of the first page from Dennis Jamiolkowski to you dated February 28, 2012.

Do you see this?

A. Yes.

Q. The subject is "Your Professional Opinion."

Do you see that?

A. I do.

Q. "Daniel, I have a request of you relying on your considerable experience in the field

of microscopy, especially SEM, and most of all on the imaging of surgical threads including polypropylene.

"I would like you to review the paper," and it lists the title of the Clave article. Correct?

A. Yes.

Q. And it was attached to that. Correct?

A. Yes.

Q. And then in all caps, "PLEASE DO NOT COMMUNICATE ANY OPINIONS VIA E-MAIL AS THESE TYPES OF COMMUNICATIONS MAY BE EASILY MISINTERPRETED BY OTHERS."

Others like me, like lawyers or a regulatory body? Who are others?

MR. DAVIS: Object to the form.

THE WITNESS: Basically by anybody who is not a part of the e-mail chain.

BY MR. ANDERSON:

Q. Well, why don't you just keep people on the part of the e-mail chain who are involved in the group?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. What's --
To your understanding, what was Dennis so worried about, about communication via e-mail?
MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. Was it such a highly sensitive topic that you guys didn't want to put much in e-mail and you wanted to keep it more verbal communication?
MR. DAVIS: Object to the form.
THE WITNESS: He was probably concerned about having a sentence taken out of context or misinterpreted.
BY MR. ANDERSON:
Q. Or as you've referred to a few times here in the deposition, worried about legal concerns, huh?
MR. DAVIS: Object to the form.
THE WITNESS: That is a consideration as well.
BY MR. ANDERSON:
Q. And then at the top there, Dennis sends an e-mail on February 29, 2012, the next day, "Dan Burkley, a Principle Scientist in our Analytical Group with extensive experience in the

field of microscopy, has had a chance to review the paper in question. (Please see the e-mail stream below)."

So evidently you received it on the 28th, reviewed it and had reviewed it by the next day.

Is that what this e-mail chains seems to indicate?

A. Yes.

Q. And is that representative of your recollection or memory as to what happened?

A. Yes.

Q. Did you get a phone call before you got this e-mail from anyone indicating that they were going to be sending this to you or that there were some issues concerning this that they were going to forward the paper to you, or did it kind of come out of the blue, as you recall?

A. No. I probably got a call from Dennis.

Q. And what did Dennis say in that phone call?

MR. DAVIS: Object to the form.

THE WITNESS: I don't recall specifically, but that he wanted my professional

opinion.
BY MR. ANDERSON:
Q. He didn't mention to you that a regulatory body was asking for information concerning this?
A. I don't recall that, no.
Q. What else do you recall about that initial phone call?
A. That he wanted me to review an article.
Q. And provide feedback?
A. Right.
Q. And once you reviewed it, did you provide that feedback to him verbally?
A. I did.
Q. And what did you tell him?
A. I made a comments on the scanning electron microscopy images in that they were very similar to the explants that I had observed from the seven-year dog study and that I believe that the cracking phenomenon was generated due to desiccation of the test article during preparation.
Q. Desiccation meaning what?
A. It basically gets dried out.
Q. Where are those SEMs from your dog

study? They're kept in your files or on your computer or in a hard copy?

A. Well, the images that were taken would have been on Polaroids, so I believe those Polaroids still exist.

Q. And where are those?

A. They should be in T106 in a research tower.

MR. DAVIS: I'm sorry, I couldn't hear.

BY MR. ANDERSON:

Q. T106 research tower?

A. Right.

Q. And where is the research tower?

A. That's located at the Somerville campus at Ethicon. It's the tallest building here.

Q. And T106, is that a room?

A. Yeah. That's a laboratory.

Q. Who maintains the laboratory?

A. I do.

Q. Is that where you go to work every day essentially?

A. In general, yeah, yeah.

Q. In other words, do you have your desk and your phone and your computer is there?

A. No, no, my office is not in there. It used to be, but no longer.

Q. Because this is the lab and you just go there for --

A. Yeah.

Q. And so if I ask you after the deposition to go to the laboratory at T106 and retrieve those images and make copies of them for your counsel, will you agree to do that, please?

A. Yes.

Q. Yes? Okay.

MR. ANDERSON: Counsel, if I could request that once he makes copies of those images, that you provide them to me, would you agree to do that?

MR. DAVIS: I'll make note of that request.

MR. ANDERSON: Given that they are Polaroids and they've been around for a little while, if the copies aren't very good, we may just want to come look at the originals. Okay?

MR. DAVIS: My only hesitancy is I'm not in charge of documents. I'll pass it along to the people in charge, I'll -- you know.

MR. ANDERSON: That's all I can ask.

You're here representing the company today.

MR. DAVIS: I understand.

MR. ANDERSON: I've got nobody else to talk to.

MR. DAVIS: That's why I say, I'll pass it along. I've got no problem with your request for the production.

MR. ANDERSON: Okay. We've got one minute left on the tape. It's probably a good time for a lunch break.

MR. DAVIS: Sure.

THE VIDEOGRAPHER: Going off the record. The time is 12:23 p.m. This is the end of Tape 2.

- - -

(A luncheon recess was taken from 12:23 p.m. to 1:17 p.m.)

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THE VIDEOGRAPHER: We are back on the record. Here marks the beginning of Volume Number 1 and Tape Number 3 in the deposition of Daniel Burkley. The time is 1:17 p.m.

BY MR. ANDERSON:

Q. Going back real briefly, those SEMs that you have from the dog study that are over in

tower -- in T106 in the research tower, you still have the SEMs of the competitor's meshes as well or the competitors' sutures as well?

A. They would be included in there, yes.

Q. Did they show cracking as well?

A. Some did, some didn't.

Q. Was it to the extent that the Prolene suture was cracked?

MR. DAVIS: Object to the form.

THE WITNESS: Not to the same degree.

BY MR. ANDERSON:

Q. And your conclusion as to what the cracking was on the Prolene suture was?

A. Well, the cracking itself I believe was an artifact from desiccation effect. But that still, the fact that the cracking, whether it's an artifact or not, it would still indicate that that surface area has undergone some type of change.

Q. And you didn't do any further studies yourself in order to see what the cause of that type of change was on the surface area. Correct?

A. No additional studies, no.

Q. And you did no additional studies, you or anyone at Ethicon, to your knowledge, of explants that came from a woman's vagina versus a

suture that came from a dog's heart. Correct?

A. I'm not aware of any such studies, no.

Q. And the Clave study actually looked at explanted polypropylene meshes, including Ethicon and Johnson & Johnson meshes, that actually had been explanted from a woman's vaginal space. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes, I believe so.

BY MR. ANDERSON:

Q. So when you go and get those SEMs, I want all the SEMs from the dog study, please, sir. Okay?

A. Yes.

Q. Do you keep anywhere in your files at the laboratory or otherwise any other SEM photographs or other analytical results from an examination of Ethicon or competitors' polypropylene meshes?

A. Well, there would be data on any other analytical testing that was done basically on any of our materials or products that were archived or logged in under a service request number or LIMs number.

Q. What about specific to degradation or

any surface irregularities of polypropylene mesh of either Ethicon's products or a competitor's products, do you have SEM photos in your lab of those?

A. There may be SEM images. SEM is not necessarily routinely done for competitive assessment but may be done on occasion.

Q. And those would be contained in the same place?

A. Yes, they would.

MR. ANDERSON: We'll request those as well, Counsel.

MR. DAVIS: Specifically what is that?

MR. ANDERSON: SEM or other analytical chemistry photographs or microphotographs of Ethicon's polypropylene fibers or meshes or sutures as well as competitors' that are also kept by Ethicon.

BY MR. ANDERSON:

Q. So after you determined that the surface cracking on the suture from the dog study was an artifact from desiccation, did you endeavor to develop any sort of analysis that would attempt to look at surface cracking or other surface

irregularities in which you could remove or take out of the equation artifacts that may be due to desiccation?

In other words, you thought that artifacts from desiccation were what caused these cracks. Did you attempt to develop any sort of scientific method or analysis that would rule out artifact or desiccation from a review of the surface of polypropylene fibers?

MR. DAVIS: Object to the form.

THE WITNESS: Well, the challenge is to try to take an explanted material and remove any attached tissue, proteins, that are on there so that you can examine the surface. Since SEM is a surface examination technique, if that's not removed, then all you're going to see is a deposit of material on top of the explant. So if you really want to get at the surface, there has to be some type of a sample preparation or treatment plan to remove the tissue and proteins. I recall one experiment where they tried to use a treatment called Soluene, which is supposed to be effective at removing tissue.

BY MR. ANDERSON:

Q. How do you spell that?

A. S-O-L-U-E-N-E.

Q. You said they attempted to use it. Who's they?

A. That would be either the -- those that were responsible for the implantation and explantation.

Q. At Ethicon?

A. Yeah. It's the surgery group.

Q. So the surgery group attempted to use Soluene to do what?

A. To remove the residual tissue and/or proteins on the implants.

Q. Did that attempt fail or have any sort of flaws?

A. Well, it did remove the surface tissues and proteins, but again, when you're drying the explants, which SEM at that time had to be done under high vacuum, you're going to end up desiccating the sample anyway. And the cracking phenomenon was still observed.

Q. I'm not a scientist, so bear with me. But if one were to attempt an analysis of explanted polypropylene fibers and wanted to use a chemical like Soluene or something else in order to remove residual tissue and protein, but they were concerned that that process itself

could lead to surface cracking, in order to rule out whether or not the Soluene or some other chemical that's being used to remove that residue, to rule out that it is causing the cracking, you could put that on a pristine sample and then do the analysis. If you don't see the cracking on the pristine sample but you see it on the other, wouldn't that lead one to believe that the cracking may be due to something other than the Soluene?

MR. DAVIS: Object to the form.

THE WITNESS: Well, that experiment would indicate that the solvent, or the Soluene in this case, does not affect the polypropylene itself.

BY MR. ANDERSON:

Q. Right.

A. It still indicates -- you know, as I said before, the evidence, the fact that you see cracking may be an artifact, but the fact -- whether it's an artifact or not, it still indicates that that surface, something has happened to it.

Q. That's right. And that's my point, is that if you wanted to make sure that the surface cracking of an explanted polypropylene was not due to the solvent to remove the tissue and the protein, you could use that solvent on a pristine mesh and if

you don't see the same cracking, that would lead the scientists to look into other factors that may have caused the cracking.

Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: No. I would only indicate that the solvent -- that that treatment is not affecting the unimpacted areas of the polypropylene fiber. The impacted area, in other words, the area that's undergone some type of change, that change would not still be completely understood. It's possible that it may not have been cracked in vivo, but the cracking could have been generated during the desiccation process.

BY MR. ANDERSON:

Q. Well, that's my point. Maybe we're not communicating well.

If you take a polypropylene fiber that is pristine, in other words, it has not been implanted, and you dip it in Soluene and you observe it under SEM and you don't see surface cracking --

A. Right.

Q. -- and you take an explanted mesh and/or fiber and you put it in Soluene and there is surface cracking, that would lead the scientist to

at least go down a course of, well, if the Soluene didn't cause it, what did. Correct?

A. Right.

Q. Okay. That's my point.

So if you wanted to determine whether or not, for instance, the suture that came out of the dog heart had surface cracking due to desiccation from the residue --

A. From the sample preparation.

Q. -- from the sample preparation, you could use the same sample preparation on a pristine fiber. And if you don't see the cracking, that might lead you to believe, ah, it's not artifact due to desiccation, it may be due to something else, let's do some more testing.

Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: It would indicate that there is a surface area that's been affected. How to characterize that effectively is still a challenge. The Soluene is effective in removing the tissue and the proteins, and you do see, you know, an affected surface that's cracking. What's not completely understood is whether the cracking is originally present in the implanted device or

whether the cracking was generated during the sample prep. It still represents that that surface -- that something has happened to that surface, but the state of that surface in vivo is still not completely understood.

BY MR. ANDERSON:

Q. That's right.

And when we don't completely understand something that may cause a failure of a particular implantable medical device, one thing we can do is study that. Correct?

A. Yes.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. And to your knowledge, Ethicon never studied that in order to determine as to whether or not this surface cracking was due to preparation versus some in vivo action. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Well, work on the explants was done to try to determine if there were better ways to isolate or, excuse me, to separate proteins and/or tissue, so -- and even with the presence of the cracking, you know, some testing was done to try to understand, okay, what is exactly

there, you know, regardless of the fact that it is cracked, what does it look like, you know, what kind of characteristics does it have.

BY MR. ANDERSON:

Q. Well, "some testing was done to try to understand, okay, what is exactly there, you know, regardless of the fact that it is cracked, what does it look like, you know, what kind of characteristics does it have."

That doesn't tell me anything. What I'm trying to find out, sir, it's more of a yes or no question. Okay?

After you determined that in your opinion this dog suture had cracking that was due to the preparation of the sample versus something else, what did you, Dan Burkley, do or another analytical scientist or someone at Ethicon, in order to do a different study, to say, okay, I want to find out if pristine samples have this kind of cracking after this same preparation so that you could determine whether or not this was actually in vivo degradation or in vivo cracking that was going on versus something due to the sample preparation. That's what I'm talking about. So it's a yes or a no.

Were other studies done after that,

yes or no?

MR. DAVIS: Object to the form.

THE WITNESS: Other testing was done on those same explants.

BY MR. ANDERSON:

Q. Okay.

What testing was that? Because I've not seen those documents. I saw the seven-year dog study and the result of that.

Is --

Was there something done after that seven-year dog study?

A. The seven-year dog study would have included information such as molecular weight. There would have been some physical testing as well.

Q. What do you mean by some physical testing?

A. Like tensile testing.

Q. So is it your opinion that if there is surface cracking of a polypropylene fiber, if it still has the same strength it had before going in, that surface cracking is not due to in vivo degradation?

A. No, that's not necessarily -- that's -- I wouldn't necessarily conclude that, no.

Q. Right.

Because that seemed to be the hypothesis that you were working under the last time you and I met, and we never could communicate on it, so I wanted to make sure that that wasn't what you were saying. That just because the tensile testing matches from prior to implantation to after explantation, that surface cracking can't be due to degradation in vivo just because they have the same tensile strength?

A. No.

Q. Is that right?

A. No.

MR. DAVIS: Object to the form.

THE WITNESS: No, that's correct.

BY MR. ANDERSON:

Q. Okay.

A. It only indicates that what is -- what areas of the surface that are being affected apparently have no impact on the performance of the suture.

Q. The performance of the suture, yes, but you didn't do any further studies to see what might be happening with the performance of the suture vis-à-vis the foreign body reaction and what

was happening in the woman's vaginal space with surgical meshes, did you?

MR. DAVIS: Object to the form.

THE WITNESS: No studies of the latter nature that you had indicated were done, to my knowledge.

BY MR. ANDERSON:

Q. And if the credo at Johnson & Johnson and Ethicon stands for a proposition that patient safety is a priority, would you agree with me that it's not in keeping with the credo if you don't do the further study to determine whether or not there is in fact surface cracking and degradation of the polypropylene fibers when it's in a woman's vagina?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. It's not in keeping with the credo if you don't follow that up. Do you agree?

MR. DAVIS: Object to the form.

THE WITNESS: That's subject to interpretation.

BY MR. ANDERSON:

Q. Yeah. And you're the guy that is in the seat to interpret today. I apologize, but that's just the nature of the process.

And so if you are aware that there's surface cracking, you believe that -- from a suture from a dog's heart that it might be due to desiccation or artifact from the preparation of the sample, shouldn't women who are going to have polypropylene fibers implanted permanently in their vaginas be able to trust that your company would follow up that study to see if in fact these polypropylene fibers were degrading in their pelvises versus it being just some artifact of preparation on an explant?

MR. DAVIS: Object to the form.

THE WITNESS: Well, the study that was done as part of a competitive assessment had indicated that after seven years, the physical strength and molecular weight of the material was essentially unchanged. So if there's any kind of degradation going on, it's relatively insignificant at that point.

BY MR. ANDERSON:

Q. That was your conclusion as a result of a suture that -- a suture is 2 or 3 centimeters long. Right?

A. It depends on the nature of the explant. Some of the explants were inches long.

Q. Okay.

So let's use that. Let's say inches long.

A. Uh-huh.

Q. Shorter than this piece of paper?

A. Probably, yes.

Q. About like that?

A. Possibly, yeah.

Q. We're also talking about something that's the size of essentially fishing line, just so the jury has some relevance?

A. Right. That's correct.

Q. So a strand of fishing line this long that was sutured into a dog's heart, you made a conclusion that the cracking that was in that suture was due to sample preparation and did no further studies to determine whether or not a surgical mesh implanted in women's vaginas would also undergo that same kind of degradation, did you?

MR. DAVIS: Object to the form.

THE WITNESS: The data obtained indicated that the device did not suffer any significant loss in molecular weight or in its tensile properties. So in terms of its function, the surface degradation or, say, change in the

surface, appeared to be limited and insignificant.
BY MR. ANDERSON:
Q. And this is a few inches of a single fiber. And the mesh that goes into a woman's pelvis is hundreds of yards long. Correct?
A. It could be, yes.
Q. Right.
And you never did a test on that much polypropylene in a woman's vaginal space to look at explanted meshes to see if they actually underwent surface degradation -- surface cracking due to degradation versus surface cracking due to treatment in order to examine it, did you?
MR. DAVIS: Object to the form.
THE WITNESS: Not to my knowledge, no.
BY MR. ANDERSON:
Q. But that was done by Clave and his colleagues. Correct?
MR. DAVIS: Object to the form.
THE WITNESS: Yeah. Investigations of that type were done.
BY MR. ANDERSON:
Q. Right.
And in response to reviewing that,

you used a seven-year dog study from 25 years ago with an SEM analysis of one strand of fiber a few inches long, you used the results of those tests to tell a foreign regulatory body, don't worry about the safety of our pelvic floor meshes in terms of degradation because we've got this 25-year-old study.

That's what you told them?

A. Essentially --

MR. DAVIS: Wait. Object to the form.

BY MR. ANDERSON:

Q. Essentially what?

A. Essentially we -- the question was on the material. The material is Prolene or polypropylene. The suture study that was done is on Prolene suture. And the study on the Prolene fiber could be applied, since it's used in a mesh product, you could leverage that type of a study to make a comment on polypropylene mesh.

Q. It's not in keeping with Ethicon's credo of putting patient safety as a priority to rely on one 25-year-old dog study with one suture from a cardiac implantation to say to a regulatory agency, our surgical meshes for the pelvic floor

don't degrade over the life of the product. That's not in keeping with the credo, is it?

MR. DAVIS: Object to the form.

THE WITNESS: I would challenge that statement.

BY MR. ANDERSON:

Q. You said that the Clave study showed the beginnings of degradation. Correct? That's what you said?

A. Yeah. There was some surface areas that indicated that some change was going on.

Q. Well --

A. It's characterized by cracking under SEM, but it's not clear if the cracking truly does exist in vivo. I believe that the cracking is generated as part of the sample prep and the desiccation effect.

Q. So you didn't testify earlier that the Clave study indicated the beginnings of degradation of the polypropylene fibers?

MR. DAVIS: Object to the form.

THE WITNESS: No. I indicated that the cracking was most likely generated as an artifact from the sample preparation.

BY MR. ANDERSON:

Q. So you came to the same conclusion that you did 25 years prior when you saw a suture and you saw some cracking there and you said, I believe it's the same thing, the Clave team is seeing what we saw 25 years ago, surface cracking due to sample preparation.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no; am I right?

A. Yeah. The surface cracking that they illustrated in the SEM looks to be the same as we examined -- as I observed with the seven-year dog study.

Q. You didn't do any follow-up testing of your own of surgically explanted meshes from a woman's pelvis in order to come to that conclusion. Correct? Correct?

A. No. I did not do any studies on polypropylene mesh used in a woman's pelvis, no.

Q. You said that that dog study was done for purposes of competitive comparison. Correct?

A. Yes.

Q. It wasn't done in order to determine patient safety. Correct?

A. To my knowledge, it was done for a

competitive assessment.

Q. Right.

And you told us earlier that you were not made aware that this work that you were doing on the Clave study in March of 2012 was going to a foreign regulatory agency. Correct?

A. That's correct. I was not aware of that.

Q. Now that you are aware that it was going to a foreign regulatory agency that we've established is there to try to protect patient safety, do you believe that further studies are warranted to look at possible surface degradation of explanted Ethicon polypropylene meshes?

MR. DAVIS: Object to the form.

THE WITNESS: Based on the data that I have seen, both from the seven-year dog study and the Clave article, I'm still confident that polypropylene mesh or polypropylene sutures as a nonabsorbable product are safe and efficacious.

BY MR. ANDERSON:

Q. I asked you at your last deposition, I said, were you aware that Ethicon's pathology consultant for the last 30 years, Bern Klosterhalfen from Duren, Germany, analyzed hundreds of explanted

mesh samples. And you said you weren't aware of that.

Do you remember that testimony?

A. That's correct, I was not aware of that.

Q. And I asked you if it would have been helpful for you, when yu had this meeting in March of 2012, to have seen what he said about the degradation of polypropylene fibers.

Do you remember that?

A. Yes. That information could have been useful.

Q. So after the deposition, did you go and ask your attorney or anyone in the company, did you say, could somebody provide me with what Dr. Klosterhalfen had to say about hundreds of explanted mesh samples when he looked at them?

MR. DAVIS: Let me insert an objection.

MR. ANDERSON: Okay. Forget the attorney part.

MR. DAVIS: Yeah. I instruct you not to answer with respect to communications with the attorney.

MR. ANDERSON: Let me clean up the

question and you won't even have to object.
BY MR. ANDERSON:
Q. After that deposition, I assume you went and talked to your colleagues and said, hey, Mr. Anderson said something about Dr. Klosterhalfen having an analysis of explanted mesh samples.
A. I had no conversations with anyone.
Q. So you didn't go and look that up. Correct?
A. No, I did not.
Q. Why not?
A. For legal implications, I wanted to wait until after this -- these trials and litigation were completed.
Q. How in the world -- strike that.
What legal implications would there be for you to go and to at least satisfy your own curiosity --
MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. -- as to whether or not Dr. Klosterhalfen had seen degradation in explanted mesh?
MR. DAVIS: Object to the form.
THE WITNESS: I don't know, but I

didn't want to find out the hard way.

BY MR. ANDERSON:

Q. When it comes to the safety of tens of thousands of women regarding whether or not polypropylene is degrading in their pelvis, shouldn't that be a greater concern than whether or not there might be legal implications for you doing this investigation?

MR. DAVIS: Object to the form.

THE WITNESS: I'm sure it's a great concern, and I'm sure that people from the preclinical and clinical area would be looking into that. I work in an analytical chemistry area. That's outside my area of expertise.

BY MR. ANDERSON:

Q. Oh. It's not outside your area of expertise, though, because they came to you as an expert in analytical chemistry --

A. Right.

Q. -- to weigh in on a response to the Clave article.

A. Yes.

Q. And they wanted your expertise as to whether or not you knew anything about surface cracking or degradation of polypropylene fibers.

Correct?

A. Well, to comment on the SEM data that they provided.

Q. Right.

So I asked you at your deposition, would you have liked to have the data from Dr. Klosterhalfen, and you said yes, that would have been good to have. Correct?

A. For the discussion of the group that we had --

Q. Correct?

A. For the discussion of the group that we had.

Q. Well, now that you know that this information was actually being provided to a regulatory agency who is concerned with women's safety long term having these implanted in their bodies, don't you believe it would be in keeping with the credo for you or someone else to provide that information of Dr. Klosterhalfen to this regulatory agency?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That's a yes or a no.

A. I can't -- I'm uncertain what I

would -- how I would respond to that.

Q. Well, I'm asking you now.

MR. DAVIS: And I object to the form.

MR. ANDERSON: Fine.

THE WITNESS: That's information that the preclinical and clinical experts would have certainly considered in their response.

BY MR. ANDERSON:

Q. Well, this is talking about your response.

You were the expert on the team from analytical chemistry --

A. Right. And I was --

Q. Just one second.

-- to discuss SEM photos. So I'm not talking about preclinical or clinical.

A. Right.

Q. I'm talking about you, the 34-year employee who they came to to talk about SEM photos of this.

A. Uh-huh.

Q. You said that it would have been nice to have had Dr. Klosterhalfen's information as part of that discussion.

So I'm asking you now, wouldn't it be

nice for you to take that information or discuss that in another meeting and decide whether or not you need to amend your response back to this regulatory agency?

MR. DAVIS: Object to the form.

THE WITNESS: It would be interesting information to have. I don't know if the information would have directly impacted the response or not.

BY MR. ANDERSON:

Q. Well, you don't know because you haven't looked at it?

A. That's correct.

MR. DAVIS: Object to the form.

- - -

(Deposition Exhibit No. T-274, E-mail chain, top one dated 05 Mar 2012, Bates stamped ETH.MESH.04937874 through ETH.MESH.04937876, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. Plaintiff's T-274.

If you look at the bottom of this page, the last four digits are 7874. And this is an

e-mail from Laura Vellucci again, March 5, 2012. You're copied on that. Do you see that?

A. Yes.

Q. And it says, "Brian, Piet and Aaron, I would like to send the following e-mail to Clare Huntington in response to her e-mail below. It will include the response prepared by Dennis, Dan and Sandy as an attachment. Please review the e-mail below and attached response. I would be grateful if you could send any comments to me today as I would like to send a reply to Clare on Tuesday or Wednesday.

"Sandy/Dennis and Dan -- I added header" and "footer and minor editing (tradename et cetera). Please let me know if you have any issue with my edits."

Then there's an e-mail to Ms. Huntington, saying, "I shared your e-mail regarding the inert nature of polypropylene mesh used in vaginal mesh products with Ethicon scientists who have expertise in analytical chemistry" -- that would be you. Correct?

A. Yes.

Q. -- "mesh technology and material biocompatibility. They have provided a brief

summary of some of the testing performed that demonstrates the biocompatibility of polypropylene material and its inert properties."

Do you see that?

A. Yes.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Do you remember now receiving --

And then if you look on the second page, which would be 7875, we do see in fact at the end of this e-mail string in which she had -- Laura Vellucci had said, I'm sending the following e-mail below to Clare Huntington. And then that's the one that we read just a few minutes ago.

Do you see that? "Dear Mark," at the very bottom, and then it carries over to the next page? Do you see that?

A. Which section?

Q. The very bottom of the document that ends in 7875.

A. Okay.

Q. "Dear Mark," and then on the next page, this was Clare Huntington at MHRA.

A. Yes.

Q. So does this refresh your

recollection that you did in fact receive an e-mail from the team telling you that Clare Huntington at MHRA was requesting this information of your group?

A. Yes. I -- yes. I was part of this e-mail string that includes that information, yes.

Q. So you were in fact made aware that the MHRA had sent a request to your company and that the information you'd be providing would be going to a regulatory body in the UK. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: No. I didn't recognize what the MHRA was at that time, no.

BY MR. ANDERSON:

Q. Did you ask anybody when you received this e-mail, who is Clare Huntington and what's the MHRA?

A. No.

Q. In the meetings that you were at, no one discussed the fact that Clare Huntington was with a governmental regulatory body in the UK and that's why you guys were meeting in the first place, to conduct this response?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of that being specifically discussed, no.

BY MR. ANDERSON:

Q. I show you Plaintiff's Exhibit T-275, which ends with 2397.

- - -

(Deposition Exhibit No. T-275, Response to e-mail from C. Huntington, March 6, 2012, Bates stamped ETH.MESH.07212397 and ETH.MESH.07212398, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. This document has at the top, "Response to e-mail from Clare Huntington," up in those brackets at the very, very top. Do you see that?

A. Yeah.

Q. It says, "Response to e-mail from Clare Huntington." Do you see that?

A. Yes.

Q. And then you see just below that in bold type, "Response to e-mail from Clare Huntington 26 January 2012...with attached publication."

Do you see that?

A. Yes.

Q. And then the second page has a space

for you to -- for your signature line. Correct?

A. That's correct.

Q. And ultimately, you signed this document. Correct?

A. I did.

Q. And when you signed that and you saw Clare Huntington in two different places, did it pique your curiosity as who in the world Clare Huntington was?

A. Well, she was the contact that Laura Vellucci wanted to respond to.

Q. Right.

And did you ask who in the world Clare Huntington was, what organization she was with?

MR. DAVIS: Object to the form.

THE WITNESS: No, I did not.

BY MR. ANDERSON:

Q. Do you see in the second paragraph beginning, "The safety and inertness of the fiber"?

A. Yes.

Q. The second sentence, "In compliance with regulatory mandate, ETHICON has established a complaint reporting system: the Worldwide Customer Quality system. With PROLENE suture, there have

been no observations of fiber degradation in complaints received and/or products returned."

Do you see that?

A. Yes.

Q. That wasn't entirely true, was it?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. You did have in fact have four examples of mesh that had been claimed to be degraded, you just didn't have enough in your file to confirm whether or not it was true; isn't that right?

MR. DAVIS: Object to the form.

THE WITNESS: I don't recall.

BY MR. ANDERSON:

Q. Then you see down on the final paragraph there on that page, you see, "In an infected field and/or a site of chronic inflammation, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species. Polymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed."

Do you see that?

A. Yes.

Q. So in fact, you're saying in this response to the UK federal regulatory authority that polymers may be subject to surface degradation due to these oxygen species and free radicals, but the impact has not been clinical assessed. Right?

MR. DAVIS: Object to the form.

THE WITNESS: Yes, that's essentially what it says.

BY MR. ANDERSON:

Q. If in fact polymers like the polypropylene in Ethicon and J&J's surgical meshes for the pelvic floor are degrading due to free radicals, other reactive oxygen species or some other in vivo action, it would be in keeping with your credo of putting patient safety first to actually do a study to determine whether or not this occurs?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Do you agree to that?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That's a yes or no question.

Do you agree to that?

A. I do not -- I'm sorry, rephrase that.

Q. I'll just repeat the question.
A. Yeah, repeat it. Yeah.
Q. If in fact the polymers, like the poly -- dadgummit. Too fast.
MR. ANDERSON: Now you have to do it.
- - -
(The court reporter read the pertinent part of the record.)
- - -
MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. Yes or no?
A. No, I don't agree with that conclusion. The reason I don't agree with that conclusion is that the extent of the degradation is not known, or in the instances where we've seen it, it's very limited or insignificant.
Q. Well, the extent is not known because you haven't done the studies. You haven't looked at -- in Ethicon, you haven't looked at explanted mesh from women's pelvises.
MR. DAVIS: Object to the form.
BY MR. ANDERSON:
Q. You told the jury that already.
A. No, but we --

MR. DAVIS: Wait. Wait a second.

Object to the form.

THE WITNESS: No, but we've looked at explanted sutures.

BY MR. ANDERSON:

Q. 25 years ago in a dog study, one suture from the cardiac?

A. Seven years in a dog, 25 years ago should be equivalent to seven years in a dog now.

Q. So at the time, though, you didn't know whether or not it was due to some sort of desiccation due to the cleaning. That's my whole point is you've never done a study to look at explanted pelvic floor meshes in order to determine whether or not there is surface degradation due to reactive oxygen species, have you?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That's my question.

A. No, I'm not aware of any additional studies beyond the dog study that investigates that specifically.

Q. And my point is, a multibillion dollar company like Johnson & Johnson, with all its resources, if it wanted to keep with its credo of

putting patient safety first, and in this case, women's safety and health for the life of their pelvis, you should have done that study to either rule out or confirm that some in vivo action was causing surface degradation of the polypropylene in their body. True?

A. I'd have --

MR. DAVIS: Wait a second. Wait a second.

Okay. Then I object to the form.

THE WITNESS: I'd have to defer to the clinical and preclinical experts who would have access to that -- to far more data than I do to make that type of determination.

BY MR. ANDERSON:

Q. With all due respect, you can't have it both ways is my position. You can't have it both ways. You can't tell us a minute ago that based upon our seven-year dog study of a suture in the heart it didn't have any clinical implications in patient safety, and then when I say, wouldn't a better study, and if you're really putting patient safety first, be to look at explanted meshes, and then you defer that to clinical. You can't have it both ways. Which way is it?

MR. DAVIS: I object to the form.

THE WITNESS: The comments I made were concerned about the SEM information, SEM data and the phenomenon of the surface cracking, whether that was an artifact or whether, you know, it truly does exist in the in vivo state, which is not -- which I am indicating -- which I have indicated it's my position that it's an artifact generated during sample prep.

Now, I do admit that the fact that you see the cracking, whether it's an artifact or not, does indicate that that surface that it's observed on, that something has happened to it. All right? Something that's not completely understood. But from the suture study, the overall molecular weight and tensile strength have not been negatively impacted.

There's also clinical data on existing Prolene products that show the product to be safe and efficacious. So consequently, if it's a nonabsorbable material, unless there's, again, other information that strongly suggests that there's a degradation concern to be -- you know, to investigate, I believe there's enough information that doesn't warrant a specific degradation study.

BY MR. ANDERSON:

Q. The only data that you have specific to SEM --

A. Yes.

Q. -- is your dog study from the '80s in which you concluded that it must be due to sample preparation, and looking at a piece of paper, the Clave study, not the actual SEM photos, a piece of paper, and saying what I see on that piece of paper looks like what I saw on a suture 25 years ago, therefore, no study needed, no problem with the women, we feel confident that our product is safe and efficacious. That's what you're telling this jury?

MR. DAVIS: Object to the form.

THE WITNESS: That information, along with the other information from the other experts, we, therefore, conclude that our product is still safe and efficacious.

BY MR. ANDERSON:

Q. What other information from other experts? I mean, it's one thing to say that. It's another -- I need hard facts here.

A. It would be Dennis and Sandy.

Q. And what did Dennis and Sandy do in

terms of looking at whether free radicals and other reactive oxygen species were leading to surface degradation, which may or may not impact women? What did they do?

MR. DAVIS: Object to the form.

THE WITNESS: You know, they made their comments concerning the safety and inertness of the fibers as demonstrated by 40 years of clinical experience.

BY MR. ANDERSON:

Q. You certainly don't have 40 years of clinical experience as of 2012 of putting hundreds of yards of polypropylene material in a woman's vagina, do you, sir?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

A. There's 40-plus years of --

Q. I'm sorry, I've got to object. It's a yes or no question. And I'm entitled to that if you can give it. If you say I can't answer your question, that's fine. But it is a yes or no question, and I am entitled to get that.

MR. DAVIS: And you're also entitled to explain. But if can be answered yes or no, you

know, answer it.

MR. ANDERSON: Thank you.

THE WITNESS: I would say no with respect to the mesh products, but for the Prolene line of products, there is a 40-plus year history.

BY MR. ANDERSON:

Q. And in that 40-year plus history, the only time you ever looked at surface degradation of your product was in the '80s with one suture from a dog's heart. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That's the only study that I've looked at, yes.

BY MR. ANDERSON:

Q. So out of this 40 years of clinical experience, you have one piece of data in terms of one test that you did 25 years before this article came out. Correct?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Correct?

A. Well, it's not just one test, but it would be several tests done during the --

Q. During one study?

A. Yes, a seven-year study.

Q. Henri Clave, one of the authors, was an Ethicon consultant.

You or nobody on the team contacted him, did you?

MR. DAVIS: Object to the form.

THE WITNESS: I am not aware if anybody on the team contacted him.

BY MR. ANDERSON:

Q. You never saw the actual SEM photos that are contained in the article, did you?

MR. DAVIS: Object to the form.

THE WITNESS: I only saw what was reprinted in the article.

BY MR. ANDERSON:

Q. Did you provide this information to the team that's in the beginning of the final paragraph of this page, "In an infected field and/or a site of chronic inflammation, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species," and then the next sentence, "Polymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed"? Did you provide that information?

MR. DAVIS: Object to the form.

THE WITNESS: I was -- I participated in the discussion, but I believe Dennis brought that up.

BY MR. ANDERSON:

Q. And what did Dennis do in terms of studies that he looked at or actual testing by your company to come to those conclusions that were ultimately sent to this foreign regulatory agency? Please tell the jury.

A. Well, that would have been a discussion, again, between Sandy and Dennis and I about the types of foreign body reactions that can occur and the different mechanisms that are used on the cellular and microcellular level during those reactions.

Q. Okay.

So my question is, what did Dennis, and now you've expanded it to Dennis and Sandy and me.

A. Right.

Q. What did you do in terms of studies that looked at actual testing by your company to come to those conclusions that were ultimately sent to this foreign regulatory agency? Your answer said, there would have been a discussion about this.

Okay. That's a discussion.

A. Yes.

Q. My question is, what testing did you look at or perform? What literature was used in support of this, to support these statements that you're making to this regulatory body? That's what I want to know.

MR. DAVIS: Object to the form.

THE WITNESS: I did not conduct any specific tests, and I don't recall citing any specific literature.

BY MR. ANDERSON:

Q. So if we take those statements right there that were made after a discussion --

A. Yes.

Q. -- and not after any literature search or testing, as you've just testified, if an infected field -- the more bacteria in an infected or contaminated field and the greater the chronic inflammation, then the greater the chance of surface degradation due to these oxidative species, would you agree with that? In other words, the more infection, the more chronic inflammation, the greater the risk of degradation. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes, I agree with that concept.

BY MR. ANDERSON:

Q. Okay.

And your suture study that you did in a dog heart, that was not in a contaminated field in the way that surgical meshes in a woman's vagina are. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: No, it was not done in a contaminated field.

BY MR. ANDERSON:

Q. In fact, a woman's vagina has all kinds of bacteria, strep A, candida, gram-negative, a lot of bacteria in a clean contaminated field that simply doesn't exist in a dog's heart. You agree with that. Right?

MR. DAVIS: Object to the form.

THE WITNESS: That sounds plausible. I don't recall during the dog study whether there were any infected sites or not.

BY MR. ANDERSON:

Q. So if you want to compare apples to apples instead of apples to oranges, you wouldn't use a suture from a noncontaminated field to compare

to hundreds of yards of suture material in a clean contaminated field of a woman's vagina?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

MR. DAVIS: Object to the form.

THE WITNESS: That depends if you're trying to compare different types of infection versus -- well, from an infection point of view, I would agree with that comparison. But in each of these instances, even a foreign body reaction can be chronic inflammation. And even in those circumstances, it's not unexpected that you could have free radicals and other reactive oxygen species.

BY MR. ANDERSON:

Q. Well, my question is, the greater the chronic inflammatory response, so if you have a severe inflammatory response and you have mesh that is implanted into a bacterial field, it increases the risk of degradation of the polypropylene. True?

MR. DAVIS: Object to the form.

THE WITNESS: It could increase the risk.

BY MR. ANDERSON:

Q. Sure.

And your suture material in a dog's heart did not have the same bacterial field or chronic inflammatory response that surgical mesh in a woman's pelvis would. Agree?

A. It probably would not.

Q. So you are comparing apples to oranges in common vernacular when you're comparing a suture from a dog heart to surgical mesh in a woman's pelvis vis-à-vis infection and chronic inflammation. True?

MR. DAVIS: Object to the form.

THE WITNESS: No, I disagree with that statement. They're all examples of infection or chronic inflammation.

BY MR. ANDERSON:

Q. Yes, but the --

We just established that there are a lot more bacteria in the contaminated field of a woman's vaginal space than there was one suture in a dog's heart. Correct?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. We established that, yes or no?

A. There would be more inflammation,

yes, relatively more inflammation. Correct.

Q. And infection?

A. And infection.

Q. And the more infection and the more inflammation, as we've just established, the greater likelihood of degradation?

MR. DAVIS: Object to the form.

THE WITNESS: The greater likelihood.

BY MR. ANDERSON:

Q. Right.

A. But not necessarily guaranteed.

Q. Right.

And so the way we find that out as scientists is what? We study. Correct?

A. You can.

Q. But you didn't. You didn't. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: We didn't do that type of comparison study, no. But they're -- like I said, they're all examples of infected fields or chronic infection.

BY MR. ANDERSON:

Q. In fact, infection and chronic inflammation were two of the potential causes listed

by the Clave authors in their study as to what was causing the degradation of the polypropylene meshes that were explanted from women's pelvises in their study. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Possibly, yeah.

BY MR. ANDERSON:

Q. Not possibly, it either was or it wasn't.

So my question is, those were two of the potential causes that were listed by the Clave authors in their study as to what was causing the surface degradation of the polypropylene in their study. True?

MR. DAVIS: Object to the form.

THE WITNESS: I'd have to review the article to be sure.

BY MR. ANDERSON:

Q. Okay. We'll look at that in a minute then.

I want to show you Plaintiff's Exhibit T-276.

- - -

(Deposition Exhibit No. T-276, Memo dated March 12, 2012, Bates stamped

ETH.MESH.07205369 and ETH.MESH.07205370, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. 5369.

Now, the last exhibit we looked at, T-275, was the unsigned version of this document. Correct?

A. Yes.

Q. And if you turn to page 2 of this T-276, it is the signed version. Correct?

A. Yes.

Q. And if you go down and we take the last document and put it up on the left, first page. Okay. If you can reverse those and highlight the last paragraph on both.

If you look at your document there and you compare it to the one that you just had before you?

A. Yes.

Q. Do you want to pull that one out, too, for me, please?

In the final signed version, if you look at the last paragraph, I don't see the language, maybe I'm just missing it and you can help

me.

Who decided -- let me strike that. Let me go back.

Who made the final decision as to what the wording would be in this response?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. And by who, it could be a group decision as far as I know, but which person or persons at Ethicon were responsible for the final language that was going to be sent to Clare Huntington of the UK regulatory agency, MHRA?

A. Well, the document would have been -- would have had Dennis and Sandy and myself contributing towards the document. I don't recall who edited the final version.

Q. I haven't seen anywhere in either version where your team told this person at MHRA, we have never done a study at Ethicon in these 40-plus years where we actually looked at explanted vaginal meshes and compared them to pristine meshes in order to determine whether or not we have found surface degradation or similar surface anomalies. You didn't tell her that, did you?

MR. DAVIS: Object to the form.

THE WITNESS: Not that specific statement, no.

BY MR. ANDERSON:

Q. And you didn't tell her that we have one of the top, if not the top, pathologists, histopathologists in the world on surgical meshes who has sent us data regarding his view on the degradation of explanted vaginal meshes, did you?

MR. DAVIS: Object to the form.

THE WITNESS: Not specifically stated in this document, no.

BY MR. ANDERSON:

Q. Not even generally stated in this document. Correct?

A. Correct.

Q. As this group was meeting to determine what kind of response would be given based upon the Clave article, did anyone offer the suggestion that perhaps we should reach out to our top pathologist who's been looking at our meshes for 30 years and ask him his opinion on the degradation of surgically implanted meshes into a woman's pelvis?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of such a

discussion.
BY MR. ANDERSON:
Q. Don't you think that in order to be in compliance with your internal credo, also just good science, it would have made sense to have reached out to your pathologist who's looked at your explanted meshes and the explanted meshes of other manufacturers in order to determine whether or not you needed to give a thorough response of whether or not you've seen surface degradation of your polypropylene?
MR. DAVIS: Object to the form.
THE WITNESS: I would leave that up to the opinion of our toxicologists and pathologists that were at the Somerville site.
BY MR. ANDERSON:
Q. And please tell me which toxicologists and pathologists were involved in these e-mail strings?
A. Well, Sandy Savidge would be the preclinical representative, so ultimately it would be her call.
Q. Well, preclinical doesn't necessarily look at once a product has been put in by a clinician and it's been explanted, she's not

necessarily involved with that aspect of the business. Correct?

A. No.

Q. I mean, that's correct. Correct?

A. Right. She's not typically involved with that aspect, that's correct.

Q. Right.

So tell me who on the team is someone who would have had access to that information. Strike that.

You said a minute ago that decision would have been made by someone else in preclinical or clinical?

A. Yes.

Q. So what I'm asking is, who here would actually be involved in the -- in working with pathologists and histopathologists for explanted material for humans?

MR. DAVIS: Object to the form.

THE WITNESS: I believe it would be Sandy, but I could be wrong.

BY MR. ANDERSON:

Q. Can we agree that this was not a thorough investigation of Ethicon's knowledge base concerning whether or not explanted meshes from the

pelvis show degradation if your team did not reach out to your pathologist who has actually looked at your explanted meshes for decades? Would you say it's not a thorough review?

MR. DAVIS: Object to the form.

THE WITNESS: I would not agree with that statement.

BY MR. ANDERSON:

Q. Do you believe that patients in the UK who are relying upon their regulatory agency and the company Johnson & Johnson/Ethicon who sold them products that were going to be permanently implanted in their body, do you think that they had a right to know and to have information concerning whether or not other women had explanted mesh showing degradation of polypropylene in their vaginas as well?

MR. DAVIS: Object to the form.

THE WITNESS: If they wanted to look at such information, I don't know if that type of information is available or not.

MR. ANDERSON: Motion to strike as nonresponsive.

BY MR. ANDERSON:

Q. I asked you, if you believe that

patients, women, in the UK who were relying upon their regulatory body to be a gatekeeper for safety of medical devices in their country, do you believe those women had a right to expect that your company would provide thorough and accurate information to this regulatory body concerning whether or not polypropylene meshes degrade in a woman's pelvis?

MR. DAVIS: Object to the form.

THE WITNESS: Well, they would certainly -- well, my opinion is that they could expect that, you know, proper product safety information would have been provided to the regulatory body.

BY MR. ANDERSON:

Q. How about if the specific product safety information concerns Ethicon's knowledge of its explanted meshes showing degradation by their top pathologist, do you think that might be information they'd want their regulatory body to know?

MR. DAVIS: Object to the form.

THE WITNESS: It might depend on the circumstances and number of incidences observed.

BY MR. ANDERSON:

Q. Can I get a yes or a no to my

question?

A. Well --

Q. Do women in this country or the UK, can they rightfully expect that the regulatory agencies who are charged with their safety are being provided with thorough and accurate information by your company as to whether or not polypropylene may degrade in their pelvises?

MR. DAVIS: Object to the form.

THE WITNESS: Yes, I think they are getting the proper information from Ethicon to the regulatory body.

BY MR. ANDERSON:

Q. You think they're getting proper information.

Proper information would also include thorough information, for instance, when you're doing an investigation on degradation, either do your own study or look to your own consultants and look at their explants. That would be thorough and proper information, not just relying on a seven-year dog study from 25 years ago. Can we at least agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: You'd want to consider

information that you had that's been generated in the past as well as the present.

BY MR. ANDERSON:

Q. Right.

And if part of that information that's been generated in the past is your pathologist and your -- strike that.

Maybe I should just take it off because it's...

Yes. And if part of the information that's been generated in the past is information that Ethicon has access to from its own pathologist who has looked at explanted samples from a woman's vagina and it shows degradation, that's information that should be passed along to a regulatory body so that they can protect the safety of women in whom these are going to be implanted. Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: Not necessarily. It depends on the context and the circumstances and the specific type of information and whether it applies.

BY MR. ANDERSON:

Q. And none of those, the context, nor the circumstances, nor the specific type of

information, at least vis-à-vis Dr. Klosterhalfen, was ever considered by your group?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That was looking at this in March of 2012. Agreed?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know what information Sandy or Dennis considered from that particular article. I can only answer from my own point of view.

BY MR. ANDERSON:

Q. If there was a failure of your team to reach out to Dr. Klosterhalfen or to other people within your company to find out what information you had on explanted meshes from either hernia or the pelvis, that would have been a violation of your credo in terms of putting patient safety first. Would you agree to that?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: No, I don't necessarily agree with that.

MR. ANDERSON: Clave article, Plaintiff's T-277.

- - -

(Deposition Exhibit No. T-277, Article entitled "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants," Arnaud Clave, et al., 10 pages, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. Before we go to that one, I'm going to show you Plaintiff's Exhibit 278.

- - -

(Deposition Exhibit No. T-278, E-mail chain, top one dated 07 Mar 2012, Bates stamped ETH.MESH.07226404 and ETH.MESH.07226405, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. The last Bates numbers are 6404. If you look at the second page of this document, it's an e-mail from you to Lynn Meyer on March 7, 2012. Do you see that?

A. Yes.

Q. It says "Any progress on my questions?"

What questions were those?

A. Questions whether or not there were any -- let's see. Let me refresh my memory here.

I wanted to know if there were any product complaint records of preabsorption or degradation.

Q. Right. We talked about this a few minutes ago.

In your final response to the MHRA, you said, "In the 40 plus" -- I need that. Can I have that?

So you were deciding whether or not you could put the language -- if you look at the middle of the first page of this, you were trying to decide whether or not you were going to -- strike that.

You asked the question of whether or not there was any complaints on degradation or preabsorption?

A. Correct.

Q. And they went back and they did in fact found -- find four complaints regarding Prolene

sutures that were under degradation or preabsorption. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. And it says, and none of those were confirmed.

And so then you say in e-mail to Dennis Jamiolkowski, Sandy and Laura on March 7, 2012, "From a search that went" back as far" as 1991, only four complaints were found concerning PROLENE suture or mesh under the categories 'degradation' or 'pre-absorption,'" and "none of those were confirmed.

"So, although there have been complaints made on PROLENE about 'degradation' or 'pre-absorption,' none were confirmed.

"Therefore, you could state that 'In the 40+ year history of PROLENE, there has not been a single confirmed complaint about degradation or absorption.'"

Do you see that?

A. Yes, I do.

Q. Why not just tell the agency that you'd had four unconfirmed reports of degradation or

preabsorption?

MR. DAVIS: Object to the form.

THE WITNESS: You could -- that could have been done.

BY MR. ANDERSON:

Q. But it wasn't done, was it?

A. No.

Q. Because it sounded better just to say that there's not been a single confirmed complaint about degradation or absorption?

A. Both are true.

MR. DAVIS: Wait, wait, wait. Object to the form.

BY MR. ANDERSON:

Q. Yeah.

One is true without telling the whole story so that you're technically right, but you didn't provide all the information to them concerning the fact that you did have four complaints of degradation.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Correct?

A. The only difference between the two statements is that in the second one it doesn't

indicate how many unconfirmed complaints were logged in.

Q. You didn't do it because you didn't -- you wanted to wordsmith it in a way that sounded the best for your company instead of providing them with all the information. That's the truth. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: The only piece of information that's missing is that there were a total of four complaints made, of which none were confirmed. Considering 40 years of the product history to have only four complaints, period, is pretty darn small. And considering that none of them were confirmed...

BY MR. ANDERSON:

Q. And some, they tried to go back into an old obsolete paper system in Germany, and they couldn't even get a complete file on some of the events. Correct?

A. That is correct. There is a file -- there is a complaint file that is incomplete apparently. But still, none of the complaints were confirmed.

Q. So then above that, Dennis sends an

e-mail to Laura that says, "Although we could make the statement that Dan suggested, I think we need to make" it "crystal clear that polypropylene is not 100 percent inert in all clinical situations."

Do you see that?

A. Yes, I do.

Q. Do you agree with the statement that polypropylene is not 100 percent inert in all clinical situations?

A. It depends on how you define "clinically inert."

Q. Well, I've heard of chemically inert and biologically inert, but I've certainly never heard of clinically inert.

Is this a new phrase you've come up with or is that something you guys use at Ethicon?

MR. DAVIS: Object to the form.

THE WITNESS: Well, as the statement was, "We need to make" it "crystal clear that polypropylene is not 100 percent inert in all clinical situations."

BY MR. ANDERSON:

Q. That means in some clinical situations it actually degrades. Correct?

MR. DAVIS: Wait. I think he was

still trying to answer the question.
BY MR. ANDERSON:
Q. Were you still trying to answer the question?
MR. DAVIS: I may be wrong, but...
THE WITNESS: No. We can move on.
MR. DAVIS: Okay.
THE WITNESS: I'm sorry, your question was?
MR. DAVIS: I apologize.
BY MR. ANDERSON:
Q. So this statement by definition is, polypropylene is not inert in all clinical situations. Correct?
A. Yes, that's what that statement indicates.
Q. In what clinical situations did your group determine, through its own testing, validation or literature review where polypropylene may degrade and not be inert in the human body?
MR. DAVIS: Object to the form.
THE WITNESS: Could you repeat that one more time, please?
BY MR. ANDERSON:
Q. In what clinical situations did your

group determine through its own testing, validation or literature review where polypropylene may degrade and not be inert in the human body?

A. I believe that was -- I believe that was acknowledging scenarios where significant infection was present, where you could -- where it would -- where you could expect the possibility of free radicals and oxygen.

Q. What's your basis for making that statement, sir?

A. Based on the discussion and the response that we made.

Q. So based upon what you just said --

A. Uh-huh.

Q. -- you would have to agree with the Clave authors that in some clinical situations, polypropylene is not inert and it does degrade.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. True?

A. I would agree that there are some -- there is some evidence that some of the polypropylene surfaces do undergo some change. That's not totally understood.

Q. Okay. Not an answer to my question,

so I'll ask it again.

Would you agree with the authors of the Clave paper that in some clinical situations, implanted surgical polypropylene mesh in human beings can degrade and is not inert?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

A. I would say it was subject to some slight degrees of surface degradation, again, which is not completely understood.

Q. And it could be better understood if your company undertook the testing of this of its own products that are permanently implanted in women. True?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

A. If such a study -- if such a study were done, it could possibly give more information about it.

Q. But your company has not spent the money nor taken the time to do that study. Correct?

A. I'm not aware of any such study being planned.

MR. ANDERSON: We can take a break.

THE VIDEOGRAPHER: Going off the record. The time is 2:39 p.m. This is the end of Tape 3.

- - -

(A recess was taken from 2:39 p.m. to 2:58 p.m.)

- - -

THE VIDEOGRAPHER: We are back on the record. Here marks the beginning of Volume 1 and Tape Number 4 in the deposition of Daniel Burkley. The time is 2:58 p.m.

BY MR. ANDERSON:

Q. So real briefly, of this group of people who were meeting to discuss Clave, we had Dan Burkley, that's you, from analytical characterization. Correct?

A. Yes.

Q. Sandy Savidge from preclinical?

A. Yes.

Q. Laura Vellucci from what department?

A. Regulatory affairs.

Q. Dennis Jamiolkowski from?

A. Suture technology.

Q. Anyone else that was regularly at

these meetings or involved in this analysis?

A. No, no. I believe it was just the four of us.

Q. And after that response was sent off to the regulatory body in the UK, have there been any further phone calls, e-mails or meetings concerning the Clave article of which you have been involved in or of which you have been aware?

A. No, none that I've been involved in and none that I'm aware of.

Q. Okay.

So did you have a chance to look at the Clave article, which we marked as Plaintiff's Exhibit T-277? That's the article we've been discussing at length here today. Correct?

A. Yep, yep.

MR. DAVIS: Let me just note my objection for the record. This was an exhibit to his last deposition and reviewed thoroughly, but I'm not going to stop you. I'm just noting my objection.

MR. ANDERSON: I appreciate that. And one of the reasons we're going into it in a little bit more detail is because we received new documents since the time of his deposition and which

his name was on, so either we didn't get all of the custodial file or we received it in a later production, and that includes a number of the exhibits that we've used today and other information. And so it made it necessary for us to not replow old ground, hopefully, maybe a little bit, but to also have an opportunity with the benefit of formerly unproduced documents to ask those questions. But I note your objection for the record. Thank you.

BY MR. ANDERSON:

Q. If you look at the second page of this -- actually, let's -- I'm sorry, let's go back to the first.

If you look under the abstract portion, under "Methods," it says, "A sample."

You had it right.

"Methods." "A sample of 100 implants explanted from patients due to complications was examined to evaluate the relative degradation characteristics of polypropylene and PET prosthetics."

And then at the top of the next paragraph, going all the way through "Conclusions." It looks like they did SEM, FTIR, which we discussed

earlier, as well as differential scanning calorimetry, DSC.

Do you see that?

A. Yes.

Q. Now, do you ever perform DSC as part of your duties at Ethicon?

A. No, I do not.

Q. Do you have a machine at Ethicon to perform DSC?

A. There is a DSC within analytical characterization.

Q. Under "Conclusions," "This is the first study to evaluate synthetic implants used in a vaginal approach for pelvic floor reinforcement. The study provides evidence contrary to published literature characterizing polypropylene as inert in such applications. Additionally, the study suggests the need for clinical trials comparatively investigating the performance of new types of monofilament prosthetics, such as those compromising PET."

Do you see that?

A. Yes.

Q. So at least according to this, this article in January of 2010 written by these authors,

was the first one to study that the synthetic implants that had been explanted from a vaginal approach for pelvic floor reinforcement. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. When your group met, did you find any other studies prior to this one or after this one where scientists studied and evaluated synthetic explants for pelvic floor reinforcement?

A. I don't recall of any studies prior to this one. I don't know if there had been other studies since this one.

Q. In order to do a thorough investigation of this problem and to provide a thorough and accurate response to the regulatory body, it would have been a good thing for your group to do a literature search. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. Did you do one?

A. I did not do a literature search, no.

Q. Did Laura, Dennis or Sandy do one?

A. I don't know.

Q. Did you ask them at any of the meetings, words to the effect of hey, guys, if we're going to provide a response to Clave, shouldn't we look to the literature to see if there's any other similar studies for vaginal explants?

A. I did not ask the question, but it's conceivable that that could have been discussed at a meeting where I was not present.

Q. And there's a whole host of references in the back of this document.

Did you or Sandy or Dennis or Laura take the opportunity to evaluate and analyze any of those bibliographical references listed in the back, of which there are 24?

A. I'm familiar with reference 16.

Q. And did you bring reference 16 to the group's -- you said you're familiar with it.

My question was, as part of your review in coming up with a response to this regulatory body, did you review any articles, so are you in response to saying that, yes, we looked at reference 16?

A. I looked at reference 16 but the group did not.

Q. What did reference 16 from 1994, the

Martin Yang article, "Infrared spectroscopy of the photoxidation of a polyethylene nonwoven fabric," tell you?

A. Well, it demonstrated that photooxidation of a polyolefin, such as polyethylene, it's certainly possible, and some of the IR absorbances that you could observe with it. It's an infrared study, basically, to look at photooxidation of polyethylene fabric.

Q. So that study told you that if you look at infrared spectroscopy of this polyolefin, that you could in fact -- that there was degradation noted in that study?

A. You could see -- yes, you could see the oxidative degradation by infrared. You could pick up the infrared absorbances specifically relating to photooxidation.

Q. Did you raise that to the group's attention?

A. No, I did not.

Q. Why not?

A. It's work I'm familiar with. We've done our own photooxidation studies on polypropylene back in the '80s, so I am familiar with oxidation of polypropylene or photooxidation of polypropylene, I

should say.

Q. What is photooxidation of polypropylene?

A. Basically you're exposing the polypropylene fiber to high intensity light to -- in an air or oxygen-filled environment and over time, seeing the effects of that exposure.

Q. Of course, when polypropylene surgical meshes are inserted into a woman's vagina, it's not going to be in an air environment. Correct?

A. No, not an air environment.

Q. So really reviewing a photooxidation study of polyethylene didn't tell you much in terms of whether or not your polypropylene meshes for the pelvis degrade in the human body?

A. Correct.

Q. An article that would have been more specific to your research and the mission that you had in trying to determine whether or not your polypropylene meshes show degradation and how to respond to this regulatory body would have probably been something like reference 20, Costello, "Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single

patient."

Can we agree that that may have provided more valuable information than looking at IR spectroscopy of polyethylene that's exposed to air?

MR. DAVIS: Object to the form.

THE WITNESS: Possibly, possibly.

BY MR. ANDERSON:

Q. But you didn't look at that nor raise that to the group's attention, nor did anyone else raise it, did they?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know if anyone else raised it. I certainly didn't raise it and I didn't -- I was not part of a discussion about that.

BY MR. ANDERSON:

Q. So if you look at page 2 of this article, under the right-hand column under "Scanning electron microscope analysis," they did a morphological analysis of explants as well as the pristine control mesh samples. Correct?

A. Yes.

Q. Prior to the doing the imaging, both the explants as well as the pristine samples were fixed and preserved in a solution of cacodylate

buffer, then they were rinsed in a buffer and then post fixed.

Do you see that?

A. Yes.

Q. Then they were rinsed with distilled water, dehydrated with ethanol solutions of increasing concentrations, dried using hexamethyldisilazane and then sputtered with gold prior to the SEM analysis. Correct?

A. Yes.

Q. When you read this portion of Costello, was it your opinion that any part of this preparation led to the surface cracking and peeling as noted in the photographs contained within this article?

A. The desiccation effect, when they did the exchanges with ethanol, you know, after it was rinsed with distilled water, that was a possibility that that desiccation effect and/or put in a high vacuum environment, those could have been opportunities of sample manipulation that may have caused that artifact.

Q. Could have been.

But in fact in this study what they found is, and the reason that they looked at the

pristine samples, was so that they could show that the pristine samples in fact were not degradaded or have -- I'm sorry, were not subject to surface cracking or peeling as a result of this fixation method. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: The pristine samples would not, because they can withstand this type of sample preparation. What's not clear is whether the surfaces that were changed could stand this type of sample preparation.

BY MR. ANDERSON:

Q. Have you ever done any studies or reviewed any studies wherein this type of sample preparation was applied to explants and it was determined that it was causing surface cracking versus in vivo degradation?

A. Not a specific study, no.

Q. So your conclusion that this may have possibly caused the surface cracking was just based upon general scientific knowledge you have?

MR. DAVIS: Object to the form.

THE WITNESS: Well, what would have -- I'm sorry.

What would have been clarifying and

useful information is if they had done any optical examinations after each step of the sample preparation to determine if there were any alterations to the surface.

BY MR. ANDERSON:

Q. But you have no data and no studies that you can point to that says more likely than not, the cracking that we see in the photos in this article is due to ethanol or a high vacuum environment versus in vivo degradation?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That's the truth. Correct? Yes or no?

A. No, I have no definitive studies specifically designed to evaluate whether it's an artifact -- whether it's generated as an artifact or whether it's present in the original in vivo environment.

Q. So it was conjecture on your part as to whether or not ethanol or high vacuum environment led to some of the surface cracking that was seen on SEM?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. It's conjecture?
A. It's my hypothesis.
Q. And you did nothing by way of testing other explanted samples or any sort of testing with any of this treatment method in order to confirm that hypothesis, did you, sir?
A. No, I had no such explants available to do such a test with or do such a comparison with.
Q. And that goes back to my earlier question.
If you had no explants, why didn't you or the group reach out and ask for the explants from Dr. Klosterhalfen?
MR. DAVIS: Object to the form.
THE WITNESS: That's an interesting proposal. But at the time that this was done, which was written in, what, 2009?
BY MR. ANDERSON:
Q. Published in 2010.
A. Yeah. Well, those explants would be pretty old by then.
Q. What if he had already done the analysis and you had it in your own files?
MR. DAVIS: Object to the form.
BY MR. ANDERSON:

Q. That would have been something that you would have liked to have seen. Right?

MR. DAVIS: Object to the form.

THE WITNESS: If he did that evaluation, yes.

BY MR. ANDERSON:

Q. And that would have been a thorough investigation by your company as to whether or not your polypropylene product degrades in a woman's pelvis. Yes?

MR. DAVIS: Object to the form.

THE WITNESS: It would be another piece of information to evaluate. Whether it represents a thorough -- a thorough investigation is conjecture.

BY MR. ANDERSON:

Q. Well, which is more scientifically valid, sir, your conjecture based on no data whatsoever that the surface cracking was due to ethanol or a high vacuum environment or reaching out to someone who had actual explants and had done analysis of them for your company? Which one is more scientifically valid?

MR. DAVIS: Object to the form.

THE WITNESS: Well --

BY MR. ANDERSON:

Q. Between those two, please answer my question.

Your conjecture, which is what you said earlier, that it was your conjecture.

A. Right. My conjecture is based on the explants that I did back in -- from 1985 to 1992.

Q. None of those were vaginal explants, were they?

A. No. But they were explants.

Q. And we've also determined that vaginal explants are in a bacterial environmental that has greater inflammatory response than other parts of the body. Correct?

A. Correct. But it still is an inflammatory or chronic inflammation environment, and you're still talking about polypropylene fibers.

Q. Just so the jury understands, what you're telling them under oath today is that some studies you did back in the '80s are just as valid as explanted Ethicon products that were analyzed by your pathologist of 30 years in Germany.

Is that what you're telling the jury?

MR. DAVIS: Object to the form.

THE WITNESS: I'm saying that that

information should be considered and can be just as valid.

BY MR. ANDERSON:

Q. And the -- what did you in the '80s was you looked at a suture coming out of a dog's heart?

A. I did.

Q. And that's more valid than looking at hundreds of explants and the analysis of them by Ethicon's pathologist.

Is that what you're telling the jury?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not saying it's more valid. I'm saying it's just as valid to examine those explants as it is from examining mesh in a vaginal site.

MR. DAVIS: Slow down just a little bit. I know it's getting late. Just pause in case I have an objection.

THE WITNESS: Okay. Sorry.

- - -

(A discussion off the record occurred.)

- - -

BY MR. ANDERSON:

Q. If you look at the next page -- let me ask you this. Let me go back a minute.

I'm still trying to communicate with you and get to some understanding of -- and unpack your answers a little bit on this comparing a pristine sample that's been treated in the exact same manner that an explant has been treated. And I believe your testimony has been, well, the ethanol or the high vacuum environment or both would have a different effect on pristine polypropylene than it would on explanted polypropylene.

Do I basically have that summarized correctly?

A. I'm saying it would have no impact on the pristine polypropylene.

Q. And why would it have an impact on the explant that it wouldn't have on the pristine? They're the exact same material.

A. That would indicate that that surface has somehow changed.

Q. I don't understand your answer. Why, if you -- strike that.

If you have the same polypropylene fibers from the same manufacturer, one undergoes the treatment that we saw on page 2 of this study, the

explant undergoes the exact same treatment. And of that treatment, you said that the ethanol or the high vacuum environment may be leading to -- possibly be leading to the surface cracking. Okay?

A. Yes.

Q. What is it about the explanted mesh that when treated with the ethanol or the high vacuum environment might lead to surface cracking, whereas the control or pristine sample would not show that?

A. The pristine sample would still be -- let's see. What's the best way to describe it?

The surfaces where the cracking is observed does represent the fact that that surface has undergone some type of change as compared to the pristine areas of the fiber. The pristine areas of the fiber, since they haven't gone through any such change and are basically unchanged normally aren't affected by the sample prep conditions. But there is something about the surface area where the cracking is observed that does respond to the desiccation effect of the sample preparation, and therefore, it behaves differently. We see it as cracking. What's not clear is whether that cracking was present before the sample preparation treatment,

because it's obscured by the tissue and/or residual tissue from the explant. And that's my stipulation, is that the sample preparation is what's generating those cracks.

Q. Now, you said the pristine areas of the fiber.

You understand that they took a fiber out of the box, pristine --

A. Right.

Q. -- as a control?

A. Yeah.

Q. There's not some pristine part of the explant.

A. Well, there's part -- there's parts of the explant --

Q. Can I just --

A. I'm sorry.

Q. It's really hard for her, so we want to keep Ann Marie happy.

If you have a fiber that has never been put into a human body -- we'll get to that.

Clave and his colleagues are not coming up with some brand new scientific method in taking a control sample and putting them in a solution and then taking the test sample and putting

the same solution in order to determine whether or not you can remove the solution as the cause for what you're finding in the test sample. This is scientific method. This is basic laboratory practice. Can we agree to that?

MR. DAVIS: Object to the form.

THE WITNESS: The control that's used by Clave is done as a comparison with the explant. And it's been demonstrated that the sample preparation has no impact on the control. All right? And I agree that's part of the scientific method, you want to demonstrate that the control is unaffected by what you're trying to do to the sample, so -- but the control does not have the affected surface that's on the explant.

BY MR. ANDERSON:

Q. What do you mean by that?

A. I mean that there are areas on the surface that is demonstrated by SEM by the cracked regions that have undergone some type of change.

Q. How do you know that the cracked region isn't along the entire line of the polypropylene fiber?

A. Well, that would be demonstrated by what areas are present, so I mean, if -- it's a

large area that's cracked, then that's a large -- that's a larger area, surface area that's been impacted. If it's a small area, then it's a small area that's affected.

Q. The whole reason that you do this in the first place is so that you can rule out the fact -- strike that.

The reason that you use the same solution and the same method on the control as you do the test sample is so that you can rule out the fact that the solution that you used or the preparation method is not affecting the test sample. Right? Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Right. That you're not impacting the suture itself.

BY MR. ANDERSON:

Q. Right.

And so the reason they did it and the way -- reason that it's a scientific -- basic scientific method, as you've just agreed, is so that you can say, this surface degradation is not due to the sample preparation, and we know that because we used the same sample preparation on the pristine model. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That would normally be the logic pattern that's pursued. However, in this instance, all right, you're looking at some surfaces that are alleged to have degraded and/or cracked. If they have been altered, it's not understood that in the original in vivo state whether those surfaces are cracked in the in vivo state or whether those cracks are generated during dehydration of the sample. It's conceivable that in the hydrated state, that that surface could be intact and not have any cracks present.

BY MR. ANDERSON:

Q. Well, it may be conceivable, but when we look at scientific probability, if the solution and the treatment that's used on the pristine is not causing any surface cracking, and you use the same solution on the explanted mesh, the logical pattern would be that the solution is not causing the cracking, therefore, what is? And that was the basis of what they were doing. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That's -- that is their conclusion, but I'm stipulating that what has not been demonstrated is that the sample preparation

is -- has no effect at all on the affected area. It's not clear whether the cracks are generated from the sample preparation procedure of the affected areas or whether those affected areas were originally cracked in an implanted state.

BY MR. ANDERSON:

Q. So you're critical of the study and would be -- and would have a greater level of confidence as to whether or not the sample preparation caused the cracking if they had done optical microscopy during each phase of this preparation prior to SEM. Is that what you're saying?

A. Correct, correct. If they had done some type of examination after each sample step to determine if there are any artifacts being generated during the course of the sample prep, that would address my concern.

Q. But you certainly cannot, as you sit here today, rule out the fact that the surface cracking on those polypropylene fibers occurred due to in vivo degradation, can you, sir?

MR. DAVIS: Object to the form.

THE WITNESS: No. The argument I can make is that those cracks that are seen in the SEM

images may have been generated during the sample preparation.

BY MR. ANDERSON:

Q. Yes, but they -- oh, I'm sorry. Go ahead.

A. The surface area, it's still a possibility that in the implanted state, those cracks may or may not exist.

Q. Right. And I'm working on --

You're working on the negative side. I'm working on the positive side.

If we're going to say it may have been caused by the sample preparation, we have to also be able to say, scientifically and common sensically, that it may have occurred in vivo prior to the sample preparation.

A. Correct.

MR. DAVIS: Wait, wait.

Object to the form.

THE WITNESS: Yeah. I have to -- yeah. I'm open to the possibility that the cracks may be present in the in vivo state and that it needs to be determined. That's not a proven point.

BY MR. ANDERSON:

Q. But you didn't say that in your

report that went to this regulatory body that these surface cracks may be present in the in vivo state. I just can't rule it out?

A. No.

MR. DAVIS: Object to the form.

THE WITNESS: I indicated that I believe that these are generated as an artifact during the sample preparation process.

BY MR. ANDERSON:

Q. But you didn't say it may have been present in the in vivo state, I can't rule that out, did you?

MR. DAVIS: Object to the form.

THE WITNESS: No, I did not.

BY MR. ANDERSON:

Q. But that's just what you've told the jury here today. Correct? Yes or no?

MR. DAVIS: Object to the form.

THE WITNESS: I have told --

BY MR. ANDERSON:

Q. Yes or no, is that what you just told the jury?

A. I'm telling the jury, and I've told the jury on other questions, that the cracks that are generated and observed in the SEM images I

believe are artifacts from the sample preparation procedure. I cannot prove it definitively one way or the other, but from my experience with the explants, I believe that this is the case.

MR. ANDERSON: Objection, move to strike the answer as nonresponsive.

And I'm going to ask you the question again and I'll keep asking it until I get a question -- an answer to my question.

BY MR. ANDERSON:

Q. You said you told this jury those cracks may have been present in the in vivo state, I can't rule it out.

MR. DAVIS: Object to the form -- I'm sorry.

BY MR. ANDERSON:

Q. However, when you responded to the regulatory agency, you left that out, didn't you?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

MR. DAVIS: And you're free to explain.

MR. ANDERSON: Well, no. I'm free to get a yes or a no. You're welcome to follow up with

any questions you want after the deposition, but --

MR. DAVIS: I understand, but I do think he answered the question. But he can answer it again.

MR. ANDERSON: Yes or no?

THE WITNESS: Please repeat it.

- - -

(The court reporter read the pertinent part of the record.)

- - -

MR. DAVIS: Object to the form.

THE WITNESS: No, I did not make that statement.

BY MR. ANDERSON:

Q. To this regulatory body in the -- in response to this analysis.

A. No.

Q. Correct?

A. No, it's not in the response.

Q. Turn to the next page, please, under the FTIR.

And what they did there was before they did FTIR analysis, both prior and after the cleaning, they did it with some sodium hydrochloride and cyclohexane. Correct?

A. I'm sorry, where are you looking specifically?

Q. Under the FTIR analysis.

A. Yes.

Q. Now, we talked about SEM. Now I want to talk about the preparation that they did on the FTIR.

A. Okay.

Q. Okay?

They did a baseline IR spectra for all the samples.

A. Uh-huh.

Q. And then to eliminate the organic residue on the explants, they treated it with -- that's probably an O, sodium hydrochloride solution. And they washed that with deionized water, and then they were extracted with pure cyclohexane for 24 hours at room temp.

Do you see that?

A. Yes.

Q. The control samples, pristine samples of Prolene and Prolene Soft "were treated with the same protocol to determine if the cleaning process had chemically modified the material."

Do you see that?

A. I do.
Q. And this study indicates that they were not chemically altered as a result of the cleaning process. Correct?
A. Yes.
Q. So in this instance, regarding FTIR spectroscopy, you don't have any problems with the way they cleaned it as to whether or not this cleaning solution may have led to the cracking. Am I right?
MR. DAVIS: Object to the form.
THE WITNESS: What's not included here is any type of optical examination to look for any evidence of cracking during each of the sample preparation steps.
BY MR. ANDERSON:
Q. But they said afterwards, because they looked at the FTIR prior to cleaning and after cleaning in order to compare the two, and they found that there was no desiccation whatsoever as a result of the cleaning process. Correct?
A. No. They indicate that they -- that there was no chemical modifications.
Q. Can you -- I'm sorry.
A. There was no indication about whether

they're looking at cracks or not. And my -- you know, what I'm being critical of is whether or not they did any examination of the fiber during the different sample preparation steps to look at and see if there was any evidence of any cracking.

Q. But they have FTIR spectroscopy, and they looked at them prior to the solution on both the control and the sample, and then they looked at them afterwards. And on FTIR, there was no -- that the chemical treatment had little to no effect on the material. Correct?

A. Correct.

Q. So I realize you want the optical microscopy steps in here, but these people who actually did the study and took the time to look at explants, they found that it had no impact on the surface degradation and the cracking. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: For the control material, that's correct. However, they looked at the explants after the entire sample preparation segment was complete. They did not look at it during different steps. And again, my same point is, is that the cracking could have been generated as a desiccation effect on those affected surfaces

that demonstrate cracking in the SEM.

BY MR. ANDERSON:

Q. If you look at the next page, on the bottom right, next page where it says "FTIR analysis," and they did a chemical analysis?

A. Uh-huh.

Q. "The FTIR spectra of pristine Prolene and Prolene Soft, before and after the treatment with" the "sodium hydrochloride and cyclohexane, were similar to typical FTIR spectra of polypropylene reported in the literature... Therefore, the chemical treatment had little effect on the material."

Do you see that?

A. I do.

Q. So what you're saying is, it may have had some effect on the explants, you don't know, because you didn't have optical microscopy at every step to be able to look at it. Correct?

A. Correct.

Q. If the person who actually performed the FTIR analysis and the SEM analysis under oath testified a few months ago that there was no changes during the preparation of these, would you defer to the person who actually did the study versus

yourself?

MR. DAVIS: Object to the form.

THE WITNESS: I'd have to see the type of data he generated.

BY MR. ANDERSON:

Q. She.

A. She.

Q. One way you could have found out about the information or the data she generated, if you wanted to do a thorough review of Clave before reporting to a regulatory body, would have been to have contacted them, and all their names and all their locations are listed on the front page of the article on the bottom left.

Can you pull that up?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. You didn't bother to call or e-mail or write to any of these people, did you?

A. I did not, no.

Q. So instead of criticizing it based upon optimal microscopy sitting in Somerville, New Jersey looking at a piece of paper, in order to provide a thorough response to a regulatory body charged with the safety of women's pelvises, you

could have reached out to these folks and asked them what their sample methods and preparations were so that you had a better understanding of their data, couldn't you, sir?

MR. DAVIS: Object to the form.

THE WITNESS: It's conceivable. I'd have to get permission from the company to make such contact, but yes.

BY MR. ANDERSON:

Q. Well, do you think that the company would have given you permission to contact someone who's Ethicon's own consultant, Henri Clave?

A. It's quite possible.

Q. But you didn't even ask?

MR. DAVIS: Object to the form.

THE WITNESS: No, I did not.

BY MR. ANDERSON:

Q. If you wanted to do a thorough review before responding to a regulatory body, you would have reached out to these scientists and asked them the same questions I'm asking you. Right?

MR. DAVIS: Object to the form.

THE WITNESS: It's conceivable that could have been done, yes.

BY MR. ANDERSON:

Q. So if you look under -- on the third page of the document, so maybe go to the front again and then just count back three pages. Right-hand side, "Histological analysis."

They found that there were basically three types of tissue reaction around the explanted meshes. Do you see that?

A. Yes.

Q. Type 1 would be an infection where they saw PMNs. Correct?

A. PMNs?

Q. Polymorphonuclear neutrophils?

A. I'm sorry, I'm not familiar with that term.

Q. That's a hallmark cellular indication of infection in the human body in response to a foreign body reaction.

Are you familiar with that?

MR. DAVIS: Object to the form.

THE WITNESS: No. I'm not a histologist, so I'm not familiar with this area.

BY MR. ANDERSON:

Q. Nonetheless, type 1 reaction is an infection. Correct?

A. It indicates that in the article,

yes.

Q. And type 2 is chronic inflammation, where they see FBGCs or foreign body giant cells and mononuclear cells. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That's what it indicates in the article, yes.

BY MR. ANDERSON:

Q. Then type 3 was a sclerosis or a pronounced fibrosis.

And you've heard about that in terms of fibrotic encapsulation of meshes. Correct?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Have you heard about that in response to the body's foreign body reaction to meshes?

A. Well, that's the first I've seen this, sclerosis tied to fibrosis. Again, I'm not familiar with these histological terms.

Q. If we look at type 1 and type 2, type 1 being infection, type 2 being chronic inflammation, those are two of the things that you listed in your response to the regulatory agency --

A. Yes.

Q. -- as to two of the things that could

be --

Two of the things that could be related to --

Two of the things that could be related to polymer degradation in vivo. Correct?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Is that correct?

A. I'd have to look at that response.

Q. Okay. I'll go back to it.

In an infected field, that would be type 1, infection. Correct? And/or a site of chronic inflammation, that would be type 2, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species, polymers may be subject to surface degradation by these reactive species.

A. Yep.

Q. And here in these articles, these are two of the things listed that they saw in and around what they described as degraded and cracked mesh. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. So would you agree with me that if the area surrounding polypropylene mesh in a woman's vagina shows histological evidence of infection and chronic inflammation, that those two factors could lead to degradation of the polymer?

MR. DAVIS: Object to the form.

THE WITNESS: That environment could promote or could have a population of free radicals and oxygen that could lead to some alteration of the surface.

BY MR. ANDERSON:

Q. What happens to a woman if the polypropylene in her pelvis -- strike that.

You understand that slings made out of Prolene by Ethicon in pelvic organ prolapse mesh made out of Gynemesh PS are going to be permanently implanted in a woman's pelvis. You understand that. Right?

A. Yes. They could be permanently implanted, yes.

Q. Well, that's the indication, they're supposed to be permanently implanted. Right?

A. Yes.

Q. So if a woman is 30 years old and she's implanted with one of Johnson &

Johnson/Ethicon's polypropylene surgical meshes, either for SUI or POP, can you state to a scientific certainty that that polypropylene will not degrade over the life of the product in her pelvis?

MR. DAVIS: Object to the form.

THE WITNESS: The product as designed is not absorbable, so, therefore, it should not degrade over the life of the product.

BY MR. ANDERSON:

Q. However, you've just told the jury, based upon the response that your team gave to this regulatory body in the UK, as well as based upon this study conducted by Clave, that in the presence of infection or chronic inflammation, polypropylene can in fact degrade in a woman's pelvis.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Correct?

A. There is some suggestions of surface alterations. There has been no indication that I've seen of actual product failure in terms of its strength, and from the studies that I've looked at, no evidence of overall loss in molecular weight. And in the data that's in the Clave study, their DSC indicates no significant changes between the

pristine and the explanted material. So the infrared study does show some observations of absorbances, but they cannot conclude whether this was oxidation or whether it was residual proteins or tissue. So I can't say there's any concrete evidence that there was any significant degradation present.

Q. And you don't have any concrete evidence that polypropylene doesn't degrade in a woman's pelvis either, do you?

MR. DAVIS: Object to the form.

THE WITNESS: I have only -- I have no personal data, but the company does have clinical data and preclinical data on other Prolene products.

BY MR. ANDERSON:

Q. We've gone through this before.

The only data that you have regarding degradation is a suture from a dog heart from the mid '80s when it comes to degradation and your company looking at SEMs of those. Correct, sir?

MR. DAVIS: Object to the form.

THE WITNESS: From my studies, yes.

BY MR. ANDERSON:

Q. What other degradation -- you qualified that.

I thought earlier we maintained that out of your 34 years, you've never seen any degradation studies other than -- if you called it a degradation study, it was actually a comparative study of your sutures.

So in your 34 years at Ethicon, you have not seen, nor are you aware of, any degradation studies performed by your company in order to determine whether or not polypropylene degrades in the human body?

MR. DAVIS: Object to the form.

THE WITNESS: That's correct. I am unaware of any existing studies.

BY MR. ANDERSON:

Q. Okay.

So now we're going back to your answer, because you listed all of these things. You listed clinical experience, you listed studies that were done, et cetera. I want to unpack that and get down to nuts and bolts here. Okay? So here's my question.

You were making the assumption that polypropylene will not degrade in a woman's pelvis over her lifetime on a seven-year dog study that was conducted from a suture from the dog's heart

conducted in the mid '80s when it comes to degradation?

A. That's part of --

MR. DAVIS: Wait. Object to the form.

THE WITNESS: That is part of the information I'm relying on.

BY MR. ANDERSON:

Q. If you look at the SEM photographs on page 265, the upper right says "265" and the word "degraded." If you look at those SEM photographs.

A. Uh-huh.

Q. There's a low density monofilament, like Prolene Soft, and a high density polypropylene monofilament like Prolene pictured there. Correct?

A. Yes.

Q. And on the left we see no surface cracking and no surface peeling, whereas on the right, in both, we do see surface cracking and perhaps peeling on the bottom with the high density being worse by observation than the one above it.

Can we agree to that observation of these photographs?

A. Yes.

Q. Okay.

When you saw those photographs and your team saw those photographs, was there a discussion amongst you as to what the clinical implications would be to a woman if these explants looked like this -- strike that.

These were taken out after three months. Correct? Degradation started appearing at 90 days. Correct?

A. In some instances, according to their article, yes.

Q. So if you see this kind of cracking at 30 days, if in fact this is degrading in a woman, was there a discussion as to whether or not this would have any clinical implications in 20 years?

MR. DAVIS: Object to the form.

THE WITNESS: There was a discussion relating to the seven-year dog study where surfaces -- where polypropylene sutures, and in some cases other sutures, had demonstrated this similar type of surface cracking, not only at seven years but at earlier time points.

But yet at the end of seven years, the testing done indicated that the molecular weight of the polypropylene was essentially unchanged and that the tensile strength of the suture was at least

90 percent or greater. So that indicated that although this observation is made, it's apparently a relatively insignificant effect in terms of the performance of the device.

BY MR. ANDERSON:

Q. Are you aware that Johnson & Johnson and Ethicon's own expert in this litigation, Dr. David Williams, sat in the exact chair you're sitting in a month after you testified and said that polypropylene does degrade in the human body?

MR. DAVIS: I object to the form.

BY MR. ANDERSON:

Q. Are you aware of that, sir?

MR. DAVIS: Object to the form of that.

THE WITNESS: No, I am not aware of that.

BY MR. ANDERSON:

Q. Have you read any of his articles from 1976 forward over the last 40 years regarding polypropylene degrading in the human body?

MR. DAVIS: Object to the form.

THE WITNESS: I'm aware of some articles that allege that polypropylene degrades.

BY MR. ANDERSON:

Q. He studied this for 40 years --

MR. DAVIS: Wait, wait. I think he's still answering.

BY MR. ANDERSON:

Q. Were you through?

A. No, I'm not through.

Q. Okay. Keep talking. Please, I didn't mean that disrespectfully.

A. And although these images look very graphic and they look very significant, it's been -- I've seen very similar images or even things that look worse than this, but the overall impact to the device itself appears to be minimal to no effect.

Q. You said the overall impact to the device.

What about the overall impact to the patient?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. What does surface degradation and polypropylene degrading in a woman's pelvis, what about her impact?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Tell me what that would do to a woman

in her tissue if this is in fact degrading. Forget the impact to the device. What about the impact to women?

MR. DAVIS: Object to the form.

THE WITNESS: It hasn't been established and is still not clear in my mind that the cracking phenomenon itself is present in vivo. Nonetheless, if there are surfaces that are being affected during chronic inflammation, they are localized and there is no evidence that I've seen that the performance of the device itself has been impacted by it.

BY MR. ANDERSON:

Q. Severe and chronic inflammation -- if you want to talk about impact on the device, severe and chronic inflammation can lead to fibrotic bridging and complete encapsulation of the mesh in scar tissue leading to contraction and nerve injury.

Do you understand that?

MR. DAVIS: Object to the form.

THE WITNESS: Yes.

BY MR. ANDERSON:

Q. And that's not just -- that might be localized to a site, and so would the woman's pain associated with that, too. It would be localized to

that site. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: For an infection site, yes, it would be.

BY MR. ANDERSON:

Q. And for a chronic inflammatory response as well?

A. Yes.

Q. If in fact there is a rough surface like this in the woman's tissue in an implant that is moving in tissue, that would increase the inflammatory response, would it not?

MR. DAVIS: Object to the form.

THE WITNESS: It's possible. It depends on the circumstances.

BY MR. ANDERSON:

Q. So if there's a possibility that surface cracking of polypropylene fibers increases the inflammatory response, that could also increase the amount of fibrosis in and around the implant. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: These are possibilities.

BY MR. ANDERSON:

Q. Well, we know from Ethicon's own investigation and studies that if you increase the inflammatory response, it increases the fibrosing around the implant and causes contraction and pain. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not necessarily familiar with the details of that, no. I can't make that conclusion one way or the other.

BY MR. ANDERSON:

Q. Well, here's the way, here's the thing.

Again, I'm not trying to be disrespectful, but you can't have it both ways. You can't, on the one hand, say this surface cracking and some chronic inflammation is localized and doesn't have any impact. And then when I say that your company is aware that a greater inflammatory response can cause contraction of the mesh, pain, nerve injury and erosions and say, oh, I don't know about that.

A. Well, I'm responding as an analytical chemist that has examined these types of devices and explants before. So I'm commenting on the surfaces of the explants. I'm not an expert in histology and

I'm not an expert in preclinical or clinical aspects. So when you start talking about inflammation sites and scarring, these are areas I'm unfamiliar with.

Q. Right.

With all due respect, you said that being someone who's familiar with looking at these explants and you pointed to those.

Truth is, you're not familiar with looking at any explants ever in your 34 years that came from a woman's pelvis, are you?

MR. DAVIS: Object to the form.

THE WITNESS: Not from a woman's pelvis. I am -- I have experience looking at explants from animals.

BY MR. ANDERSON:

Q. Other than the dog study, what explants from animals have you looked at under SEM?

A. I can only recall the dog explants.

Q. Okay.

So there weren't explants from animals --

MR. DAVIS: He wasn't through.

BY MR. ANDERSON:

Q. Oh.

A. I'd have to refresh my memory if I've ever looked at any other examples from any other animal types.

Q. Well, if you're going to tell the jury under oath that you have this experience by looking at explants from other animals, I have a right to ask you which animals. And all I've heard from you this time and the last time I deposed you was one dog study in the '80s.

A. Then I should correct it to say only dogs.

Q. So when you point at these pictures here, all you've looked at is one suture from a dog's heart. You haven't looked at 100 explants from women's vaginal space in order to do an SEM or an FTIR or a DSC analysis in order to determine whether or not they are degrading in a woman's pelvis, have you, sir?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Yes or no?

MR. DAVIS: Object to the form.

THE WITNESS: No, but I've looked at several explants from the dog studies at various time points. So it's not just simply one explant.

And there were other testing done besides scanning electron microscopy. Those examinations include molecular weight and physical testing.

BY MR. ANDERSON:

Q. You looked at a fiber a few inches long. That's what you looked at. Right?

A. Correct.

Q. You've mentioned molecular weight a few times, so let me ask you this.

If in fact a scientist were to perform a study and they actually spent the time, money and effort to look at explants from a woman's vagina and compare the pristine fiber of, let's say Prolene to the explanted fiber of Prolene, and there was a loss of molecular weight, there was evidence of chronic inflammation and infection, would that lead you in the direction of perhaps there was degradation of that polypropylene fiber?

MR. DAVIS: Object to the form.

THE WITNESS: The loss of molecular weight would suggest possible degradation of the Prolene.

BY MR. ANDERSON:

Q. Okay.

So you just haven't seen any studies

wherein explanted surgical polypropylene mesh was compared to pristine polypropylene mesh in which there was a drop in molecular weight of the explanted mesh that would help you out in making that determination. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I have not seen that type of evidence.

BY MR. ANDERSON:

Q. If you look at the page that has -- that says 267 up in the upper right corner, turn to the page just before that, and we're going to carry over from the bottom of the page you have your finger on there, the bottom right.

"Several hypotheses concerning the degradation of the polypropylene are described below. None of these, particularly direct oxidation, could be confirmed in this study."

And then you look at the next page, and we have small Roman numeral i, ii and iii.

Do you see those?

A. Yes.

Q. The three hypotheses for the surface degradation are "direct oxidation of the polypropylene," "fatty acid diffusion" or "oxidation

due to free radical attack."

Do you see that?

A. Yes.

Q. And free radical attack and oxidation is one of the things that's listed in Ethicon's response to Clare Huntington. Correct?

A. Yes.

Q. And one of the ways that you would see a greater free radical attack response and oxidation would be in the presence of an infected field or chronic inflammation. Correct?

A. That's one example, yes.

Q. If you look at the top right of the next column, "The chronic inflammatory reaction may infer free radical synthesis as peroxide and superoxide ions and hypochlorite acid."

Do you see that?

A. I do.

Q. The human body produces peroxide, in particular hydrogen peroxide, does it not?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. I'm sorry, that's a bad way of asking the question.

Let's take a woman. A woman's body

produces hydrogen peroxide and other strong peroxides. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know the specific circumstances where that would occur, unless that's a cellular -- extracellular response. But I'm not personally knowledgeable nor an authority to indicate whether they do or not.

BY MR. ANDERSON:

Q. So a woman's body may produce peroxides and in particular hydrogen peroxide, you just don't know?

A. I don't know. That's correct.

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. If it does, that would be one thing that would infer a free radical synthesis. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: That is one hypothesis explained here in this article, yes.

BY MR. ANDERSON:

Q. A woman also has in her vaginal space, in her body, but in this instance where the mesh is located in her vaginal space, hypochlorite acid, does she not?

MR. DAVIS: Object to the form.

THE WITNESS: I can't comment on that.

BY MR. ANDERSON:

Q. If in fact a woman has strong peroxide and hypochlorite acid in her body and it induces a chronic inflammatory reaction, that in fact could account for surface degradation of polypropylene. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: It's one hypothesis stated in this article, yes.

BY MR. ANDERSON:

Q. Well, I'm not asking if that's just a hypothesis, I'm asking you, because you have given your opinion on things, you've looked at this, some things you agree with, most you don't. So with all due respect, I'm not asking what they -- I know what they said, it's right here. I'm asking you, because you had provided a response to this agency. So that's the backdrop of my question.

A. Right, right.

Q. So if a woman has strong peroxides and hypochlorite acid that's produced and it's in and around this mesh, it can in fact lead to

degradation of the mesh --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- in some women. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: In that environment, it's possible it could have -- it could impact the surface.

BY MR. ANDERSON:

Q. In a septic environment or a contaminated environment like surgical meshes for a woman's vagina are placed, also when you have hematoma and bruising, fatty acids are produced by the woman in response to those two things that could also lead to degradation. Correct?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not -- I can't comment on that. I don't know that for a fact or not.

BY MR. ANDERSON:

Q. And if you see carboxyl groups on FTIR, that could also be related to direct oxidation of polypropylene, could it not?

MR. DAVIS: Object to the form.

THE WITNESS: It could be related to

oxidation. It could be related to residual proteins.

BY MR. ANDERSON:

Q. If we had a bacterial environment with a chronic inflammatory response in the presence of hydrochloride acid and strong peroxides like hydrogen peroxide, in some women that can in fact degrade the polypropylene in their pelvis. Would you agree with that?

MR. DAVIS: Object to the form.

THE WITNESS: In that environment, it could possibly have an impact on the surface of the polypropylene fibers.

BY MR. ANDERSON:

Q. And it could in fact cause it to degrade and lose molecular weight. Correct?

A. I do not agree with that statement.

Q. You have no basis for stating that you disagree with it other than your dog study in the '80s?

MR. DAVIS: Object to the form.

THE WITNESS: That data -- yes, I'm relying on that data.

BY MR. ANDERSON:

Q. If you look right above "Conclusion"

on page 269, it says 269 up at the top.

Right above the word "Conclusion," that last sentence, "Additional chemical analysis such as thermogravimetric analysis and molecular weight determination, specifically, would further clarify the mode of prosthetic damage."

Do you see that?

A. Yes.

Q. After you read that and before you guys decided to give a response to the UK regulatory authority, what thermogravimetric analysis and molecular weight determinations did you do on explanted meshes from a woman's pelvis?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not aware of any testing that we have done on any explanted meshes from women's pelvises.

BY MR. ANDERSON:

Q. Is it your testimony to the jury today that the reason that Johnson & Johnson and Ethicon has not conducted any degradation studies like the Clave study in which explanted Ethicon meshes have been compared to pristine Ethicon meshes is because there's no need to, we have a seven-year dog study from the '80s?

MR. DAVIS: Object to the form.

THE WITNESS: The clinical history of the Prolene line of products --

BY MR. ANDERSON:

Q. I need to know -- I need to know if that is your testimony. That's a yes or no. Because I don't want to go back through the clinical history and all those things. Quite frankly, you've had a great opportunity to lay that out on the record. I understand your story line. Okay? My question is a little different.

I don't, quite frankly, and with all due respect, care about 40 years of clinical history, because I'm talking about a very specific study here and we're talking about degradation. Okay? So that's the context of my question.

A. Right.

MR. ANDERSON: Can you read back my question, please?

- - -

(The court reporter read the pertinent part of the record.)

- - -

MR. DAVIS: And I will remind the witness that while he -- if he can answer yes or no,

he should, but he's always free to explain every answer.

MR. ANDERSON: Actually, no. I'm entitled to a yes or no, and you have the right to ask him any questions you want at the end of the deposition.

MR. DAVIS: I'm going to instruct the witness that my understanding of the rule is you are entitled to explain your answer. But if it can be answered yes or no, you should certainly do that. I agree with counsel opposite, but you do have a right to explain your answer.

MR. ANDERSON: I respectfully disagree with that and it's certainly not the rule in Ohio -- I mean the rule in New Jersey.

BY MR. ANDERSON:

Q. Go ahead. Can you answer that yes or no?

A. I can't -- I cannot answer it yes or no. The reason I can't answer it yes or no is I can't speak on behalf of the company as a business decision why they would not pursue such a study as you've indicated. If I had to speculate, I would say that it would be based -- that their decision would be based that there was not a sufficient need

at this time to warrant such a study based on the clinical information on the Prolene line of products, and the information already gathered on other studies such as the seven-year dog study, on other Prolene-type products, since they are made from the same type of polypropylene fibers.

BY MR. ANDERSON:

Q. At the time that you responded a little over a year ago to this regulatory body, did Ethicon and Johnson & Johnson have access to explanted tissue and material of its products from women?

MR. DAVIS: Object to the form.

THE WITNESS: I do not know.

BY MR. ANDERSON:

Q. Did anyone on your team reach out within the company, send a company-wide e-mail, send an e-mail to anyone in pathology, and ask, do we have any explanted mesh samples or access to our explanted mesh samples that we could perform an analysis of?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Did your team do that?

A. I'm not aware of any such inquiry.

Q. Now, Joerg Holste is your counterpart in Norderstedt, in the Ethicon Norderstedt facility. Correct?

A. He was a member of corporate product characterization, but he was stationed over in Norderstedt.

Q. And if you testified at your first deposition that he was your counterpart in Ethicon Norderstedt, any reason that you wouldn't agree with that today?

A. He was a member of the department. By counterpart, he does not have -- he did not have the same role I had within corporate product characterization. So he was -- you know, he was certainly another associate within the department.

Q. I show you Plaintiff's T-279, last four digits 6636.

- - -

(Deposition Exhibit No. T-279, Interim report mesh explants pelvic floor repair, April 2008, Bates stamped ETH.MESH.00006636, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. At the top it says "Interim report mesh explants pelvic floor repair, April 2008, Professor B. Klosterhalfen, Institute of Pathology Duren Hospital" in "Germany."

Do you see that?

A. I do.

Q. Down at the bottom, you see that this was translated by Joerg Holste in April of 2008, a senior research fellow for Ethicon in -- we just said in Norderstedt. Correct?

A. Yes, I believe that's where he's located.

Q. Okay.

Either way, Joerg Holste is an Ethicon employee?

A. He is.

Q. So he translated this document in April of 2008 of 100 explanted mesh samples. And these are mesh explants for the pelvic floor. And that, of course, is what Clave was looking at, 100 explants from the pelvic floor. Correct?

A. Yes.

Q. It says, the "most serious complication following mesh implantation in pelvic floor was mesh erosion in 80 to 90% of the cases."

It says, "Mesh erosion is nearly 100% combined with secondary mesh/surgical site infection... Developing a mesh ulceration follows this infection."

Then it says under 3, "All meshes without exception induce typical foreign body tissue reaction known from mesh implants in hernia surgery."

Number 4, "Foreign body tissue reaction FBR induces fibrosis in the mesh implant area, i.e. severe foreign body reaction is associated with severe fibrosis."

5, "Severe fibrotic tissue reaction is often associated with degenerative calcification."

Do you see that?

A. Yes.

Q. Do you think it would have been helpful for your team to have reached out to Dr. Klosterhalfen, who five years prior to you giving this response -- four years prior to you giving this response to this regulatory body, had looked at 100 explant meshes and given a report to your company about them?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. Don't you think that would have been helpful as part of your investigation?

A. It's possible that information could have been useful.

Q. Now that you've seen this report and you know that Prof. Klosterhalfen has explants, are you going to go back and suggest to your team that perhaps we should do similar Clave analysis on explanted meshes that we have under our control so that we can try to determine whether or not there's degradation of these --

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. -- that may be associated with complications in women?

MR. DAVIS: Object to the form.

THE WITNESS: Well, the issue associated with explants that are -- have already been explanted and are old is how they're being preserved, and whether or not they're preserved has an impact on the areas that we're interested in examining.

BY MR. ANDERSON:

Q. If he has evidence,

histopathologically or on any of the analyses that he has done of explanted pelvic floor meshes indicating degeneration or degradation of the polypropylene fibers, don't you think that would be information that should be provided to the regulatory body who asked you this question a year ago?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know if that particular type of information would be applicable or related to the inquiry. And the reason I say that is I'm not a clinician and I'm not -- you know, I don't have preclinical expertise to determine if these types of observations have any significance with the question about -- that the regulatory body had about the polypropylene pelvic floor mesh device.

BY MR. ANDERSON:

Q. Well, you made a statement in that -- your signed statement to this regulatory body that says, "With Prolene suture, there have been no observations of fiber degradation in complaints received and/or products returned."

If you wanted to make a full statement back to them now and say, you know what, a

year ago we told you that we don't -- we've never had any observations of fiber degradation; however, we've reached out to our pathologist in Germany who has hundreds of our explants and what we've found is there actually is degradation.

You don't have to be a clinician to be able to provide that information, do you, sir?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. And please answer my question.

A. I see --

Q. Do you have to be a clinician to provide that information, or is that something on your own you could do as part of this group that responded to this regulatory agency?

MR. DAVIS: Object to the form.

THE WITNESS: I don't know how to answer that question, because the question that you asked me before involves specific points on this memo. And my response was that, you know, I'm not a clinician and I'm not a preclinical expert to determine whether or not these observations are directly related to that. Then you started talking about fibers, fiber degeneration, but this does not talk about any kind of fiber degeneration.

BY MR. ANDERSON:

Q. I'll ask you my question again.

In order to provide a thorough, truthful and accurate response to this regulatory agency, even though it's a year after you gave your first response, wouldn't it be a responsible credo-based action to actually reach out to Prof. Klosterhalfen and ask him if he has seen in his samples evidence of degradation? That's my question.

MR. DAVIS: Object to the form.

THE WITNESS: I'd have to discuss that with the rest of the team.

BY MR. ANDERSON:

Q. Don't you think you ought to do that?

MR. DAVIS: Object to the form.

THE WITNESS: Well, it's worth consulting the team.

BY MR. ANDERSON:

Q. Can we agree, just as a basic common sensical principle of credo-based, ethical medical device manufacturing that if you've got information that may be helpful to patient safety, even if it hurts the bottom line of the company, you ought to be providing that to regulatory agencies or doctors

or patients?

MR. DAVIS: Object to the form.

THE WITNESS: I can't agree to that statement.

BY MR. ANDERSON:

Q. If you have information in the form of Ethicon/Johnson & Johnson explanted pelvic floor meshes, which have been analyzed pathologically, histopathologically and other forms of analytical characterization that are sitting in Duren, Germany, would it be credo-based, ethical conduct by your company to try to determine that information so that you could provide that information to Ms. Clare Huntington?

MR. DAVIS: Object to the form.

THE WITNESS: The observations noted in the article and that are described on here I'm sure would be evaluated by the appropriate professionals and determined, you know, whether these observations are significant enough to be included in such a discussion. But I don't have the -- you know, the overall expertise to make that kind of a judgment call.

BY MR. ANDERSON:

Q. So in other words, yes, Mr. Anderson,

in order to be an ethical, credo-based company who has patient safety first, we should reach out to Prof. Klosterhalfen to see if any of our explanted meshes show degeneration so that we can inform regulatory bodies, doctors and patients that there is a chance that polypropylene could degrade in their pelvises?

MR. DAVIS: Object to the form.

THE WITNESS: That's not my conclusion.

- - -

(Deposition Exhibit No. T-280, Intermediate Report -- Prolapse Mesh Explants 6/2009, Bates stamped ETH.MESH.02157879 and ETH.MESH.02157880, was marked for identification.)

- - -

BY MR. ANDERSON:

Q. Let's look at T-280, last four 7879. Did I give you the right one, 7879?

A. Yes.

Q. Okay.

This is a little over a year later, another intermediate report from prolapse mesh explains in June of 2009 where Prof. Klosterhalfen

is saying that he's analyzed 172 mesh explants from different manufacturers.

If you look down at number 5, "Strong fibrosis is associated with degradation" and "calcification to a greater than average extent."

Do you see that?

A. Yes. But what's not clear to me is what he means by degradation/calcification and whether that's supposed to be the same as degenerative calcification.

Q. So wouldn't it be great to have had these for your group so that you could have asked him?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. You don't know because no one asked. Correct, sir?

MR. DAVIS: Object to the form.

THE WITNESS: Well, I don't know under what circumstances this type of study was requested. And being an analytical chemist, there's a lot of information here that is outside my area of expertise.

BY MR. ANDERSON:

Q. Right.

And that's why you had different specialties on your group?

A. That's correct.

Q. And no one reached out to Prof. Klosterhalfen for this response, did they?

MR. DAVIS: Object to the form.

BY MR. ANDERSON:

Q. That you're aware of?

A. I'm not aware of that, no.

THE VIDEOGRAPHER: Going off the record. The time is 4:22 p.m. This is the end of Tape Number 4.

(Deposition adjourned at approximately 4:22 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, DANIEL F. BURKLEY, MS, have the opportunity to read and sign the deposition transcript.

_____

ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 282, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

DANIEL F. BURKLEY, MS DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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